

CHAPTER Ph 100 ORGANIZATIONAL RULES

PART Ph 101 PURPOSE AND SCOPE

Ph 101.01 Purpose and Scope. The rules of this title implement the statutory responsibilities of the New Hampshire board of pharmacy created by RSA 318, as amended, and RSA 318-B, as amended. These provisions regulate the licensing of pharmacies and pharmacists, the practice of pharmacy in the state of New Hampshire, the safekeeping and distribution of pharmaceuticals and legend drugs, and the inspection of pharmacies and other licensed and unlicensed locations where legend drugs are held, stored or offered for sale.

PART Ph 102 DEFINITIONS

Ph 102.01 Statutory Definitions Adopted. All terms used in these rules shall have the same meaning as in RSA 318:1, RSA 318-B:1 and RSA 541-A:1.

Ph 102.02 Other Definitions.

- (a) "Board" means the New Hampshire board of pharmacy created by RSA 318.
- (b) "Evidence" means all oral or documentary material received by the board. Evidence includes, but is not limited to, testimony under oath or affirmation, documents, exhibits, and sworn statements of witnesses who are unable to appear at the proceedings.
- (c) "Executive secretary" means the board's staff director, a person with delegated authority to perform administrative and clerical functions for the board.
- (d) "Licensed" means a person or place lawfully authorized to engage in the practice of pharmacy under RSA 318:18 and RSA 318:37 and includes "registered" when used to refer to pharmacists or pharmacies.
- (e) "Order" means the whole or any part of the final decision, whether affirmative, negative or declaratory in form, of the board in any matter other than rulemaking, but including licensing. An order has particularized effect on each party to the proceeding.

PART Ph 103 AGENCY ORGANIZATION

Ph 103.01 Composition. The New Hampshire board of pharmacy is composed of 7 board members, appointed by the governor and council for a term of 5 years, limited to no more than 2 consecutive terms. At least one member shall be a hospital pharmacist, and one member shall be a public member.

Ph 103.02 Officers. Annually, in September, the board members shall elect, from among their number, a president, a vice president, a secretary and a treasurer.

Ph 103.03 Address.

(a) The board shall maintain an office at 121 South Fruit Street, Concord, N.H. 03301. All correspondence with the board shall be addressed as follows:

State of New Hampshire Board of Pharmacy

121 South Fruit Street
Concord, New Hampshire 03301.

(b) The telephone number of the board shall be (603) 271-2350. The fax number shall be (603)271-2856.

Ph 103.04 Meetings.

(a) The board shall meet in its office on the third Wednesday of each month. Special meetings shall be held at the call of the president or by any officer.

(b) A majority of the board may take action by telephone poll or written ballot provided that such action is ratified at a subsequent meeting of the board.

PART Ph 104 PUBLIC INFORMATION

Ph 104.01 Records. Except as exempted by law, all records of the board may be examined by any person at the board office, during weekdays, excluding holidays, from 8:00 a.m. to 4:00 p.m.

Ph 104.02 Copies.

(a) At the time and place identified in Ph 104.01, any person examining a document may make a copy of that document by any means not injurious to the document provided that the person wishing to make the copy supplies the means of doing so in the office of the board. In the event a person does not have a means of copying those documents, the board shall make copies of the documents examined upon request.

(b) The prescribed fee for copies of documents made by this board shall be a minimum of \$5.00 which includes up to 20 pages then 0.25¢ for each additional page thereafter and shall be payable in advance by bank draft, money order, certified check or cash.

Ph 104.03 Lists of Licensees/Registrants.

(a) Instead of the examination and copying permitted by Ph 104.01 and Ph 104.02, any person may request the board to provide that person with a complete mailing list of the board's licensees/registrants. This request shall be accompanied by the prescribed fee for each list requested and shall be paid by check or money order.

(b) The fees for the lists shall be:

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| (1) Pharmacist data file by e-mail | \$125. |
| (2) Pharmacist data file on CD-ROM | \$150. |
| (3) Pharmacist pre-printed mailing labels | \$200. |
| (4) Pharmacy Technician data file by e-mail | \$125. |
| (5) Pharmacy Technician data file on CD-ROM | \$150. |
| (6) Pharmacy Technician pre-printed mailing labels | \$200. |
| (7) In-State Pharmacy data file by e-mail | \$ 75. |

(8) In-State Pharmacy data file on CD-ROM	\$100.
(9) In-State Pharmacy pre-printed mailing labels	\$150.
(10) Out-of-State Pharmacy data file by e-mail	\$ 75.
(11) Out-of-State Pharmacy data file on CD-ROM	\$100.
(12) Out-of-State Pharmacy pre-printed mailing labels	\$150.
(13) Drug Manufacturer/Wholesaler data file by e-mail	\$ 75.
(14) Drug Manufacturer/Wholesaler data file on CD-ROM	\$100.
(15) Drug Manufacturer/Wholesaler pre-printed mailing labels	\$150.

CHAPTER Ph 200 PRACTICE AND PROCEDURE

PART Ph 201 INTRODUCTION AND DEFINITIONS

Ph 201.01 Procedure Governed. This chapter governs practice and procedure before the board in both adjudicative and non-adjudicative proceedings.

Ph 201.02 Definitions.

(a) "Adjudicative proceeding" means the procedure to be followed in contested cases, as set forth in RSA 541-A:31 through RSA 541-A:36.

(b) "Board" means the New Hampshire pharmacy board.

(c) "Declaratory ruling" means a ruling by the board as to the specific applicability of any statutory provision or of any rule or order of the board.

(d) "Licensee" means a person, partnership, corporation, or any other legal or commercial entity however organized, duly licensed by the board pursuant to the provisions of RSA 318, RSA 318-B, or other applicable law.

(e) "Opponent" means any person who objects, on the grounds of public or private interest, to the approval, determination, consent, certification or authorization of any petition which the board might have under consideration.

(f) "Party" means each person named or admitted as a party, or properly seeking and entitled as a right to be admitted as a party in an adjudicative proceeding.

(g) "Presiding officer" means the board president or an individual to whom the board president has delegated the authority to preside over an adjudicative proceeding, a rehearing, or a rulemaking hearing.

(h) "Proponent" means any person who supports, on the grounds of public or private interest, the approval, determination, consent, certification or authorization of any petition which the board may have under consideration.

PART Ph 202 FILING AND SERVICE OF DOCUMENTS

Ph 202.01 Filing of Documents.

(a) A document shall be considered filed when it is actually received at the board's office in Concord and conforms to the requirements of this chapter.

(b) All documents filed shall be either originals or legible copies bearing original signatures. Only a single copy of routine correspondence, license applications, and consumer complaints against licensees shall be filed.

Ph 202.02 Subscription and Veracity of Documents.

(a) All complaints, petitions, motions, and replies filed with the board shall be signed by the proponent of the document or, if the party appears by a representative, by the representative.

(b) The signature on a document filed with the board shall constitute a certification that:

- (1) The signor has read the document;
- (2) The signor is authorized to file it;
- (3) To the best of the signor's knowledge, information, and belief, there are good grounds to support it; and
- (4) The document has not been filed for purposes of delay or harassment.

Ph 202.03 Service of Documents.

(a) Complaints against licensees of the board shall be filed with the board without service upon the licensee which is the subject of the complaint.

(b) Petitions for rulemaking and petitions for declaratory rulings shall be filed with the board without service upon other persons.

(c) All motions, replies, exhibits, memoranda, or other documents filed in an adjudicatory proceeding shall be served by the proponent upon all parties to the proceeding by:

- (1) Sending a copy of the document by U.S. mail, first class postage prepaid, addressed to the last address given to the board by the party being served, no later than the day the document is filed with the board; or
- (2) Delivering a copy of the document in hand on or before the date it is filed with the board.

(d) All notices, orders, decisions or other documents issued by the board in the course of an adjudicatory proceeding shall be served by the board upon all parties to the proceeding by either:

- (1) Sending a copy of the document by U.S. mail, first class postage prepaid, addressed to the last address given to the board by the party being served; or
- (2) Delivering a copy of the document in hand to the party.

(e) When a party has appeared by a representative, service shall be upon the representative.

(f) Except for exhibits distributed at a prehearing conference or a hearing, every document filed with the board and required to be served upon the parties to an adjudicatory proceeding shall be accompanied by a certificate of service, signed by the person making service, attesting to the method and date of service, and the persons served.

Ph 202.04 Voluntary Production of Information.

(a) Each party and intervenor shall attempt in good faith to make complete and timely response to requests for the voluntary production of information and documents relevant to the hearing.

(b) When a dispute arises concerning a request for the voluntary production of information or documents, any party or intervenor may file a motion to compel the production of the requested information or documents.

Ph 202.05 Motions to Compel Production of Information and Documents.

(a) Any party or intervenor may make a motion seeking an order for compliance with an information or document request. The motion shall be filed at least 20 days before the date scheduled for the hearing and in any event as soon as possible after receiving the notice of the hearing and failing in an attempt to obtain the requested information or documents through voluntary production.

(b) The motion to compel shall:

- (1) Set forth in detail those facts which justify the request for information or documents; and
- (2) List with specificity the information or documents being sought.

(c) Objections to motion to compel shall be filed within 10 days of the delivery of the motion.

(d) The presiding officer shall grant the motion to compel if its proponent has demonstrated that an order for compliance is necessary for a full and fair presentation of evidence at the hearing.

PART Ph 203 HEARINGS AND PROCEEDINGS

Ph 203.01 Mandatory Pre-Hearing Disclosure of Witnesses and Exhibits. At least 5 days before the hearing, the parties and intervenors shall provide to the other parties and intervenors:

(a) A list of witnesses intended to be called at the hearing including the names, their addresses and their telephone numbers;

(b) Brief summaries of the testimony of the witnesses to be called;

(c) A list of documents and exhibits intended to be offered as evidence at the hearing;

(d) A copy of each document intended to be offered as evidence at the hearing; and

(e) An offer to allow the inspection on non-documentary exhibits intended to be offered as evidence at the hearing at times and places of convenience to the parties and intervenors.

Ph 203.02 Representatives.

(a) Any person may represent himself/herself in a proceeding before the board or may be represented by an attorney or a competent individual of good character.

(b) A representative under (a) above shall be someone who:

- (1) Is an attorney holding a current and active New Hampshire license who has filed a written appearance with the board containing his or her business address and telephone number; or
- (2) Is not a New Hampshire licensed attorney, but has filed a motion for leave to appear as a representative which has been granted by the board.

(c) Motions made pursuant to Ph 203.01 (b)(2) shall:

(1) Describe the proposed representative's qualifications including, but not limited to, the following:

- a. Education;
- b. Experience serving in a representative capacity before administrative agencies, boards, or commissions; and
- c. Present employment.

(2) Provide the proposed representative's daytime address and telephone number; and

(3) Be signed by both the proposed representative and the party who would be represented.

(d) The board shall grant a motion made pursuant to Ph 203.01 (b) (2) if the proposed representative does not have a history of dishonesty or felonious acts.

(e) Nothing in this section shall be construed to permit the unauthorized practice of law.

Ph 203.03 Computation of Time. Any time period specified in this chapter shall begin with the day following the act, event, or default, and shall include the last day of the period, unless it is a Saturday, Sunday, or state legal holiday, in which event the period shall run until the end of the next day which is not a Saturday, Sunday, or state legal holiday. When the period prescribed or allowed is less than 7 days, intermediate Saturdays, Sundays, and state legal holidays shall be excluded from the computation.

Ph 203.04 Change in Allowed Times.

(a) Except where a time period is fixed by statute, a party may file a motion to change a time period which shall set forth specific facts to support their request to enlarge or shorten the time provided for the filing of any document, or advance or postpone the time set for any oral hearing, prehearing conference, or other activity.

(b) The board shall grant such motion:

- (1) If all parties consent; or
- (2) For good cause shown from the facts presented.

(c) Good cause under (b) (2) above shall include the following:

- (1) Unavoidable unavailability of witnesses, parties, their attorneys, or their authorized representatives; or

(2) Other exigent circumstances beyond the control of the parties, their attorneys, or their representatives.

(d) A consent of the parties under (b)(1) above shall be:

(1) Made in writing;

(2) Signed by all parties; and

(3) Filed with the board prior to a scheduled date or the expiration of a time period.

Ph 203.05 Recess and Adjournment.

(a) The presiding officer shall recess or adjourn any proceeding for good cause, which shall include but not be limited to the following:

(1) Other exigent business of the board;

(2) The end of the business day; or

(3) Inclement weather.

Ph 203.06 Waiver.

(a) Any interested person may request the board to waive or suspend provisions of the Ph 200 rules by filing an original and 2 copies of a petition which identifies the rule in question and sets forth specific facts and arguments which support the requested waiver.

(b) Petitions for rule waivers shall address whether:

(1) Adherence to the rule would cause the petitioner hardship. "Hardship" in this context means that because of petitioner's unique circumstances strict adherence to a rule would be unreasonable or result in unfair advantage to another party.

(2) Other good cause for waiving the rule exists, including the following:

a. Repeal or amendment of the enabling statute for provisions of rules from which a waiver is sought; or

b. Other circumstances which render a rule inapplicable, unenforceable, or illegal.

(c) If examination of the petition reveals that other persons would be substantially affected by the proposed relief, the board shall require service of the petition on such persons and advise them that they may file a reply to the petition.

(d) Petitions for waiver shall be acted upon by the board within 45 days of receipt. The board shall give written notice of the decision to all interested parties.

(e) A granted waiver shall only apply to the proceedings under review at the time of the petition.

(f) Provisions of Ph 200 rules which include provisions of New Hampshire statutes shall not be waived.

(g) A consent of the parties under (f) above shall:

- (1) Be made in writing;
- (2) Identify the specific rule provision to which the waiver applies;
- (3) Be signed by all parties; and
- (4) Be filed with the board.

Ph 203.07 Docket. The board shall maintain a docket of all proceedings, hearings, and rehearings pending before the board.

Ph 203.08 Consolidation.

(a) A party may file a motion to consolidate whenever 2 or more proceedings involve substantially similar or related issues.

(b) A motion to consolidate may include a request for a single hearing, a single decision, or both.

(c) The board shall grant a motion to consolidate upon finding that:

- (1) A requested consolidation would further the interests of fairness and efficiency; and
- (2) A requested consolidation would not impair consideration of the issues presented by each individual matter.

Ph 203.09 Severance.

(a) A party may file a motion to sever one or more issues from a proceeding and dispose of those issues in another proceeding whenever it shall appear that injury to the substantive rights of a party or undue delay might be thereby avoided.

(b) The board shall grant a motion for severance upon finding that:

- (1) A requested severance would further the interests of fairness and efficiency; and
- (2) A requested severance would not impair the proceeding from which the issue or issues are removed.

PART Ph 204 ADJUDICATIVE PROCEEDINGS

Ph 204.01 Applicability. This part shall govern adjudicative proceedings before the board.

Ph 204.02 Place of an Adjudicative Proceeding. Adjudicative proceedings before the board shall be held at the offices of the board, 121 South Fruit Street, Concord, New Hampshire.

Ph 204.03 Commencement of Adjudicative Proceeding.

(a) Pursuant to RSA 541-A:31, II, the board shall commence an adjudicative proceeding at any time as a result of the following actions by a licensee:

- (1) Failure to file requisite reports within 30 days of applicable deadlines;

- (2) Failure to pay fees or fines within 60 days of invoice date;
- (3) Engaging in licensed activity with a suspended, revoked, or expired license;
- (4) Failure to allow board personnel access, authorized by law, to the books, papers, records, files or similar documents for purposes of conducting examinations; or
- (5) Any other failure to comply with the laws, rules or orders of the board governing the licensee's activities.

Ph 204.04 Notice.

(a) Notice of an adjudicative proceeding shall be governed by the following provisions, unless otherwise provided by law:

- (1) The board shall give written notice to a party at least 30 days prior to a scheduled hearing date by first class mail, postage prepaid, or by personal service upon a party or a party's agent;
- (2) Contents of the notice shall be governed by the provisions of RSA 541-A:31, III.

Ph 204.05 Continuances.

(a) Any party or intervenor may make an oral or written motion that a hearing be delayed or continued to a later date or time.

(b) A motion for a delay or a continuance shall be granted if the presiding officer determines that a delay or continuance would assist in resolving the case fairly.

(c) If the later date, time and place are known when the hearing is being delayed or continued, the information shall be stated on the record. If the later date, time and place are not known at that time, the presiding officer shall as soon as practicable issue a written scheduling order stating the date, time and place of the delayed or continued hearing.

Ph 204.06 Emergency Orders.

(a) Pursuant to RSA 318:30-a, if the board finds that public welfare requires emergency action against a licensee, and the board incorporates a finding to that effect in an order, the board shall order the immediate suspension of a license pending an adjudicative proceeding which shall be commenced not later than 30 working days after the date of the board's order suspending the license.

(b) An emergency order shall be served upon the licensee by certified mail-return receipt requested, or by personal service upon the licensee, or by personal service upon the licensee's agent as identified on the most recent license application submitted to the board.

Ph 204.07 Intervention.

(a) A person filing a complaint which becomes the subject of a disciplinary hearing shall be served with the hearing notice and notified that he/she may petition to intervene in the proceeding.

(b) The board shall grant one or more petitions for intervention if:

(1) The petition is submitted in writing to the board, with copies mailed to all parties named in the notice of hearing, at least 3 days before the hearing;

(2) The petition states facts demonstrating that the petitioner's rights, duties, privileges, immunities or other substantial interests might be affected by the proceeding; and

(3) The interests of justice and the orderly and prompt conduct of the proceedings would not be impaired by allowing the intervention.

(c) Once granted leave to intervene, an intervenor shall enter the proceeding as it stands at the time. No portion of the proceeding shall be repeated because of the fact of intervention.

Ph 204.08 Access to Board Records.

(a) Parties shall have access to any statements, documents, or other information in the board's files pertinent to an adjudicative proceeding. However, confidential information pursuant to RSA 318:30, I, including consumer complaints and confidential material otherwise protected by law shall not be disclosed or provided to any party other than the board.

(b) The intervenor shall have access to all materials permitted by Ph 204.07 (a).

Ph 204.09 Filing Requirements. Copies of all documents, pleadings, motions, objections, requests, memorandums, correspondence, accounts, and the like, which are filed by a party with the board shall be provided to other parties to the same proceeding as follows:

(a) A party shall send copies of all documents filed by first class mail, postage prepaid, to all other parties, or shall deliver such documents in hand to all other parties; and

(b) A party shall certify compliance with Ph 204.08 (a) by submitting a certificate of service with the documents filed.

Ph 204.10 Stipulations. The parties to an adjudicative proceeding may by written stipulation agree upon facts or issues of proof relating to the subject matter of the proceeding. The stipulation shall be filed with the board and approved by the presiding officer in order to be considered in rendering a decision.

Ph 204.11 Evidence.

(a) Proceedings shall not be conducted under the rules of evidence, but the evidentiary privileges recognized by the law of New Hampshire shall apply to proceedings under this chapter.

(b) Pursuant to RSA 541-A:33, II, the board shall receive all material and relevant evidence bearing upon the subject matter of the proceeding.

(c) The presiding officer shall determine the admissibility of evidence and shall exclude irrelevant, immaterial or unduly repetitious evidence.

(d) All witnesses appearing before the board shall testify under oath or affirmation and subject to the penalties specified in RSA 641:1 and RSA 641:2.

(e) Oaths or affirmations shall be administered by the presiding officer.

Ph 204.12 Withdrawal of Presiding Officer.

(a) Upon his or her own initiative or upon the motion of any party or intervenor, the presiding officer shall withdraw from any adjudicative proceeding for good cause.

(b) Good cause shall exist if the presiding officer:

(1) Has a direct interest in the outcome of the matter, including but not limited to, a financial or family relationship with any party or intervenor;

(2) Has made statements or engaged in behavior which objectively demonstrates that he or she had prejudged the facts of the case; or

(3) Personally believes that he or she cannot fairly judge the facts of the case.

(c) Mere knowledge of the issues or acquaintance with any party, intervenor or witness shall not constitute good cause for withdrawal.

Ph 204.13 Hearing Procedure.

(a) After calling the hearing to order, the presiding officer shall identify the proceeding for the record by name and docket number, shall briefly state the nature of the proceeding, and shall request those present to identify themselves for the record.

(b) The presiding officer shall afford an opportunity for opening statements or direct testimony by the board representative and the licensee or licensee's representative.

(c) After any opening statements, the board representative shall present witnesses and exhibits, followed by presentation of witnesses and exhibits by the licensee or licensee's representative.

(d) Opportunity shall be afforded to either party to cross-examine each witness of the other party at the conclusion of the witness's direct testimony.

(e) The presiding officer shall if additional information is required pose questions to any witness during or subsequent to direct testimony or cross-examination.

(f) After all testimony and evidence is presented, the presiding officer shall allow closing statements by the board representative and by the licensee or licensee's representative.

(g) After all information has been presented, the presiding officer shall declare the hearing closed.

(h) The presiding officer shall afford intervenors the same opportunities for presenting testimony, evidence, or witnesses, and for conducting cross-examinations and for making closing statements as other parties to the proceeding.

Ph 204.14 Burden of Proof.

(a) The party asserting the affirmative of a proposition shall have the burden of proving the truth of that proposition by a preponderance of the evidence.

(b) Without limiting the generality of Ph 204.12 (a), all moving parties and all petitioners shall have the burden to show that their motion or petition should be granted.

Ph 204.15 Decisions.

(a) If the board finds that the licensee has complied with the statutory requirements and the rules adopted pursuant thereto, the board shall enter a decision favorable to the licensee.

(b) If the board finds that the licensee has not complied with the statutory requirements or any rule adopted pursuant thereto, the board shall enter a decision adverse to the licensee.

(c) The board's decision shall be set forth in writing.

(d) The decision shall include findings of fact and conclusions of law, separately stated.

(e) If any party has submitted proposed findings of fact, the board's decision shall include a ruling on each proposed finding.

(f) The board shall give written notice of decisions to parties within 7 days after the date of decision by first class mail, postage prepaid.

Ph 204.16 Failure to Appear.

(a) Failure of a licensee to appear in person or by representative at the adjudicative proceeding shall constitute a default.

(b) A default for failure to appear shall constitute:

(1) A waiver of licensee's right to an adjudicative proceeding;

(2) Admission of the facts alleged; and

(3) Consent to the board's determination on the matter.

(c) The board shall strike a default for failure to appear based upon a written request and information submitted by the licensee within 7 days after the originally scheduled hearing date which sets forth good cause. Good cause shall include illness, accident, the death of family member, or other circumstances beyond the control of the licensee.

(d) The board shall give written notice to parties of a decision either to grant or deny a request to strike a default for failure to appear within 7 days of the date of decision by first class mail, postage prepaid.

(e) If a request to strike a default for failure to appear is granted, the board shall give notice of a re-scheduled hearing in accordance with Ph 204.04.

Ph 204.17 Informal Settlement.

(a) Any informal settlement of matters by nonadjudicative processes shall be reflected in writing and made part of the record for a particular matter.

PART Ph 205 REHEARINGS AND APPEALS

Ph 205.01 Motion for Rehearing.

(a) A motion for rehearing shall be considered only after a decision or order has been made by the board.

(b) Any party to the proceeding may apply for a rehearing in respect to any matter determined in the action or proceeding, or covered or included in the order.

(c) Motions for rehearing shall be filed with the board within 30 days of the date of the final decision or order.

(d) Motions for rehearing shall set forth fully every ground upon which it is claimed that the decision or order complained of is unlawful or unreasonable, or based upon a mistake of law or fact.

(e) A party may submit a memorandum of law in support of a motion for rehearing.

Ph 205.02 Action on Motion for Rehearing.

(a) Pursuant to RSA 541:5, within 10 days of receiving a motion for rehearing, the board shall render a decision either to grant or deny the motion, or suspend the order or decision complained of pending further consideration.

(b) Pursuant to RSA 541:3, the board shall grant such motion if good reason for the rehearing is provided.

(c) Good reason shall include, but not be limited to, the following:

(1) New information which was not available at the time of hearing;

(2) A change in law relied upon by the board in reaching a decision on the hearing, including amendment or repeal of statutes or administrative rules, and changes in common law based upon decisions of the supreme court; or

(3) Other factors beyond the control of the moving party causing the decision to be unreasonable or unlawful, or to be based upon a mistake of law or fact.

(d) The board shall give written notice of decision on a motion for rehearing to the parties within 7 days after the date of decision by first class mail, postage prepaid.

(e) If a motion for rehearing is granted, the board shall give written notice to the parties at least 30 days prior to the scheduled rehearing date by first class mail, postage prepaid, or by personal service.

Ph 205.03 Burden of Proof. The burden of proof shall be on the moving party to show by preponderance of the evidence that the board's decision was unlawful or unreasonable, or was based upon a mistake of law or fact.

Ph 205.04 Decisions.

(a) The board shall issue a written decision within 20 days of the date of the rehearing which clearly states the reasons for the decision.

(b) The decision shall include information on the rights of appeal to the supreme court pursuant to RSA 541, if the decision is adverse to the party who appeals.

(c) The board shall keep a final decision in its records for at least 5 years following their dates of issuance, unless the director of the division of records management and archives of the department of state sets a different retention period pursuant to rules adopted under RSA 5:40.

PART Ph 206 DECLARATORY RULINGS

Ph 206.01 Petitions.

(a) A person may request a declaratory ruling from the board on matters within its jurisdiction by filing an original and 2 copies of a petition with the board.

(b) All petitions shall contain the following information:

- (1) The name and address of the petitioner;
- (2) The name and address of the petitioner's representative, if any;
- (3) A statement of the issue or question for which the petitioner seeks a declaratory ruling;
- (4) A statement of all relevant and material facts related to the petitioner's request; and
- (5) The identification of any statutes, rules, orders, or other legal authority which support the petitioner's request.

(c) A petition for a declaratory ruling may include the following:

- (1) Legal memoranda, supporting affidavits, tables, exhibits, and other relevant documentation; and
- (2) A statement explaining how the requested ruling would benefit the petitioner or the public at large.

Ph 206.02 Action on Petition.

(a) Within 90 days of the receipt of the petition for a declaratory ruling, the board shall:

- (1) Respond to the petitioner in writing, stating the board's declaratory ruling on the issues or questions raised in the petition; and
- (2) File the declaratory ruling with the director of legislative services in accordance with RSA 541-A:16, II (b).

PART Ph 207 RULEMAKING PETITIONS

Ph 207.01 Rulemaking Petitions.

(a) A person may request the adoption, amendment, or repeal of a board rule by filing an original and 2 copies of a rulemaking petition with the board.

(b) A rulemaking petition filed with the board shall include the following:

- (1) The name and address of the petitioner;
- (2) The name and address of the petitioner's representative, if any;
- (3) A statement of the justification for the adoption, amendment, or repeal of a rule;
- (4) Any supporting data, information, exhibits, illustrations, or other documentation;

(5) The identification of any statutes, rules, orders, or other legal authority which support the petition; and

(6) A draft of the proposed rule.

Ph 207.02 Incomplete Rulemaking Petitions.

(a) The board shall notify the petitioner of deficiencies in the petition within 15 days of the submission of a petition to adopt, amend, or repeal a rule.

(b) Any corrected petition which is filed with the board shall be deemed to be the first submission of the petition for the purposes of applicable deadlines.

Ph 207.03 Action on Rulemaking Petition.

(a) Within 30 days after the submission of a rulemaking petition, the board shall either grant or deny the petition and:

(1) Notify the petitioner in writing of a decision to deny the petition with reasons for the denial clearly stated; or

(2) Notify the petitioner in writing of a decision to grant the petition, and commence rulemaking proceedings by requesting a fiscal impact statement pursuant to RSA 541-A:5 within 120 days of receipt of the petition and continuing the proceeding in accordance with the applicable provisions of RSA 541-A:3.

(b) Any denial shall be based upon a finding by the board that:

(1) The petition for rule or amendment or repeal of an existing rule would not be consistent with established standards for the practice of pharmacy and the licensees of the board;

(2) The petition lacks rulemaking authority; or

(3) The petition is contrary to legislative intent.

PART Ph 208 RULEMAKING HEARINGS

Ph 208.01 Public Notice of Rulemaking Hearing. The board shall cause to be published in the New Hampshire Rulemaking Register a notice of its intent to conduct a rulemaking hearing pursuant to RSA 541-A:6.

Ph 208.02 Presiding Officer.

(a) The presiding officer shall:

(1) Maintain order during the rulemaking hearing, and order any person causing disorder or a disruption to the orderly conduct of the hearing to leave the hearing room;

(2) Recognize speakers who have placed their names on the speakers list;

(3) Receive all written comment that is submitted during the course of a hearing; and

(4) Adjourn the hearing.

Ph 208.03 Order of the Rulemaking Hearing. The hearing shall proceed as follows:

- (a) The presiding officer shall make opening remarks;
- (b) Proponents of the adoption, amendment or repeal of the rule shall be called by the presiding officer to provide comment;
- (c) Opponents of the adoption, amendment or repeal of the rule shall be called by the presiding officer to provide comment;
- (d) After all persons wishing to comment have been heard, the presiding officer shall receive any written comment not previously submitted to the board; and
- (e) After all written comment has been collected, the presiding officer shall make closing remarks and adjourn the hearing.

Ph 208.04 Oral Comment.

- (a) Any proponent of or opponent to the adoption, amendment or repeal of a rule may make oral comment relative to such rule at the rulemaking hearing.
- (b) In order to be recognized at the hearing, any person wishing to comment shall sign the speakers list at the hearing and wait to be called by the presiding officer.

Ph 208.05 Written Comment.

- (a) Any proponent or opponent may submit written comment to the board pertaining to the adoption, amendment or repeal of a rule.
- (b) All written comment relative to proposed rulemaking shall be submitted to the board in accordance with the notice of rulemaking, which shall set forth a deadline allowing a minimum of 5 days time after adjournment of the rulemaking hearing.
- (c) Written comment shall be submitted by filing an original and 2 copies with the board.

PART Ph 209 EXPLANATION OF ADOPTED RULES

Ph 209.01 Requests for Explanation of Adopted Rules. Any interested person may, within 30 days of the final adoption of a rule, request a written explanation of that rule by making a written request to the board including:

- (a) The name and address of the individual making the request; or
- (b) If the request is that of an organization or other entity, the name and address of such organization or entity and the name and address of the representative authorized by the organization or entity to make the request.

Ph 209.02 Contents of Explanation. The board shall, within 90 days of receiving a request in accordance with Ph 209.01, provide a written response which:

- (a) Concisely states the meaning of the rule adopted;

(b) Concisely states the principal reasons for and against the adoption of the rule in its final form; and

(c) States, if the board did so, why the board overruled any arguments and considerations presented against the rule.

CHAPTER Ph 300 LICENSING OF PHARMACISTS AND PHARMACIES

PART Ph 301 LICENSING OF PHARMACISTS BY EXAMINATION

Ph 301.01 Application.

(a) Application form Ph A-1 for licensure to practice the profession of pharmacy in New Hampshire may be obtained from, and shall be filed at, the office of the board, identified in Ph 103.03.

(b) Applicants for licensure shall submit an application for licensure that contains the following:

- (1) Name, address and telephone number of the applicant;
- (2) Date and place of birth of the applicant;
- (3) Record of convictions of violations of federal, state or local liquor or drug-related laws;
- (4) Pharmacy license disciplinary actions taken by any other state or licensing jurisdiction;
- (5) Any felony convictions;
- (6) Pharmacy college attended, graduation date and degree awarded;
- (7) Practical experience before licensure as a pharmacist;
- (8) A copy of the candidate's birth certificate;
- (9) A recent, full face photograph of the candidate;
- (10) An official final transcript sent directly from the college to the board office; and
- (11) The prescribed fee which shall be \$265.

(c) An official final transcript shall be mailed directly from the college to the board before either NAPLEX scores or New Hampshire licensure status is released, or if a foreign graduate, the foreign graduate shall have completed a transcript verification program as provided by FPGEC certification.

(d) If an official final transcript is not available prior to the examination date, the candidate shall obtain a letter, sealed with the official college seal, which shall:

- (1) State that the candidate has graduated;
- (2) Be signed and dated on or after the date of graduation by a college official authorized to make such a certification; and
- (3) Be presented to the board of pharmacy prior to admission to the examination.

(e) The photograph required by Ph 301.01 (b)(9) shall be attached to the application form in the presence of a notary public or justice of the peace.

Ph 301.02 Additional Requirements. In addition to any requirements imposed by statute, all candidates for a license to practice pharmacy in New Hampshire shall demonstrate that they possess the following qualifications:

- (a) The candidate shall be not less than 18 years of age;
- (b) The candidate shall be of good professional character as evidenced by 3 signed references, and the absence of conviction of any felony, or of a misdemeanor resulting from a violation of any drug and/or pharmacy-related law or rule;
- (c) The candidate shall have graduated with a professional pharmacy baccalaureate degree or a doctor of pharmacy degree granted by a school of pharmacy, or a college of pharmacy, or a department of a pharmacy of a university;
- (d) To meet the requirements of (c) above, the school, college or department of pharmacy, shall be accredited by the American Council on Pharmaceutical Education.
- (e) If a foreign graduate, in lieu of (c) and (d) above, the candidate shall have graduated from a foreign college of pharmacy and have obtained full certification from the FPGEC including:
 - (1) Passing the FPGEE with a score of at least 75; and
 - (2) Demonstrating proficiency in english by passing the TOEFL with a score of at least 550.
- (f) Prior to the examination date, the candidate shall have completed an internship in pharmacy which shall:
 - (1) Consist of at least 1500 hours, starting no earlier than 4 months prior to the third year of study in a college of pharmacy; and
 - (2) Consist of work predominantly related to the practice of pharmacy including, but not limited to:
 - a. The selling of drugs and medical supplies;
 - b. Interpreting, compounding, preparing and dispensing prescription orders;
 - c. Preparing pharmaceutical products; and
 - d. Keeping records and preparing reports required by federal and state statutes.
- (g) The candidate shall complete and pass the examination described in Ph 301.03.

Ph 301.03 Examination Contents. The examination required by Ph 301.02 shall be the National Association of Boards of Pharmacy Licensure Examination (NAPLEX) consisting of competency testing areas of:

- (1) Pharmacy theory;
- (2) Applied or practical pharmacy;
- (3) Pharmacology;
- (4) Mathematics and chemistry; and

(5) The current federal and state laws, regulations, and rules governing the practice of pharmacy in New Hampshire.

Ph 301.04 Scheduling of Examinations.

(a) Except as provided in (b) below, the pharmacy examination shall be administered by the board. Upon request, the board shall notify the candidate of the date of the next scheduled examination. Failure of the candidate to sit for the examination at the required time shall result in denial of the application.

(b) Instead of requiring a candidate to take the complete pharmacy examination in the state of New Hampshire, the board shall accept, as equivalent to an examination administered by the board, the score attained by a candidate on a NAPLEX examination administered by the pharmacy licensing authority of some other state, but only if:

- (1) The examination was administered in that other state in accordance with a degree of security which was equivalent to or greater than the security employed in the administration of examinations by this board;
- (2) This board receives directly from the National Association of Boards of Pharmacy the score the candidate obtained on the NAPLEX examination;
- (3) The candidate successfully completes a practice of pharmacy jurisprudence examination administered by the board and any other requirement for licensure, within a 90-day period from the date the New Hampshire application is mailed by the board office to the candidate; and
- (4) The candidate delivers to the board, with, or before, the transferred scores, the prescribed fee of \$265.

Ph 301.05 Required Examination Score. To successfully complete the examination required by Ph 301.02, the candidate shall, in the initial examination or any subsequent re-examination permitted by Ph 301.06, obtain a score of not less than 75. The passing score for the board's practice of pharmacy law examination shall be 75 and shall not be reflected in the NAPLEX examination score.

Ph 301.06 Notice and Election of Re-examination.

(a) Any candidate who fails to obtain the minimum required score may elect to retake the examination.

(b) All candidates shall notify the board in writing whether he/she elects to be re-examined. The request for re-examination shall be accompanied by the prescribed fee as established by Ph 301.01 (b)(11).

(c) Any re-examination permitted by this section shall be administered by the board. Upon request by the candidate, the board shall notify the candidate of the next available dates of re-examination.

Ph 301.07 Issuance or Denial of Original License.

(a) If a candidate timely files an application, complete in all respects, successfully completes all examinations required by Ph 301 and demonstrates the complete fulfillment of the requirements of these rules and RSA 318, the board shall issue a license to practice pharmacy.

(b) In the event a candidate for an original license to practice pharmacy in New Hampshire fails to meet the requirements of these rules, or RSA 318, or both, the board shall deliver to the applicant a written denial of the application, specifying in detail the requirement which the candidate failed to meet, and how the candidate is deficient.

PART Ph 302 LICENSING OF PHARMACISTS BY RECIPROCITY

Ph 302.01 Reciprocity.

(a) Instead of sitting for the entire licensing examination required by Ph 301.02, a candidate may transfer the actual scores he or she attained on the NAPLEX administered by a state other than New Hampshire, providing that:

- (1) The candidate was issued a license to practice the profession of pharmacy in that state by reason of that examination;
- (2) The candidate is still duly licensed and is in good standing in that state; and
- (3) All other New Hampshire pharmacist licensing requirements have been met.

Ph 302.02 Application.

(a) The preliminary application for reciprocal licensure may be obtained from the office of the board or from the National Association of Boards of Pharmacy, 1600 Feehanville Drive, Mount Prospect, Illinois, 60056, (847) 391-4406. This application shall be filed with the National Association of Boards of Pharmacy.

(b) The applicant shall include the following on the application:

- (1) Name, address and telephone number of the applicant;
- (2) Date and place of birth of the applicant;
- (3) Record of convictions of violations of federal, state or local liquor or drug-related laws;
- (4) Any disciplinary actions taken by any other state or pharmacist licensing jurisdiction against the applicant;
- (5) Any felony convictions;
- (6) Pharmacy college attended, graduation date and degree awarded;
- (7) State of original licensure as a pharmacist, license number and date of original issuance; and
- (8) Practice as a pharmacist and employment after original licensure.

(c) The candidate shall file a completed application NABP Form P provided by the National Association of Boards of Pharmacy.

Ph 302.03 Contents of Reciprocity Application.

(a) The reciprocal application for a license to practice pharmacy in this state shall consist of:

- (1) The National Association of Boards of Pharmacy (NABP) application Form P;
- (2) A copy of the candidate's birth certificate;
- (3) A recent, full-face photograph of the candidate attached to the application;
- (4) An official copy of the candidate's pharmacy college transcript mailed directly from the college to the board; or if a foreign graduate, certification from the FPGEC; and
- (5) The prescribed fee of \$265.

Ph 302.04 Requirements. In addition to any requirements imposed by statute, all candidates for licensure by reciprocity to practice pharmacy in New Hampshire shall demonstrate that they possess the following qualifications:

- (a) The candidate shall be not less than 18 years of age;
- (b) The candidate shall be of good professional character as evidenced by 3 signed references and the absence of conviction of any felony or of a misdemeanor resulting from a violation of any drug and/or pharmacy related law or rule;
- (c) The candidate shall possess a professional pharmacy baccalaureate degree or a doctor of pharmacy degree (Pharm.D.) granted by a school of pharmacy, or a college of pharmacy, or a department of pharmacy of a university; and
- (d) To meet the requirements of (c) above, the school, college or department of pharmacy, shall be accredited by the American Council on Pharmaceutical Education;
- (e) A candidate who is a foreign pharmacy graduate, in lieu of (c) and (d) above, shall provide written documentation that such candidate has:
 - (1) Obtained full certification from the FPGEC; and
 - (2) Passed NAPLEX.
- (f) The candidate shall be licensed by examination and in good standing in the state from which he or she is seeking licensure transfer;
- (g) The state from which the candidate holds a license shall grant reciprocity privileges to pharmacists licensed by examination in New Hampshire;
- (h) The examination administered by the original state of licensure required the same degree of fitness as was required in New Hampshire at that time. If the candidate graduated on or after July 1, 1978, he or she shall have successfully completed the national examination as described in Ph 301.03;
- (i) Candidates shall have obtained scores equivalent to the New Hampshire standards at the time the candidate was initially examined in the state in which he or she holds a current license; and
- (j) The candidate for a reciprocal license shall complete and pass a jurisprudence examination on the current federal and state laws and rules governing the practice of pharmacy in the state of New Hampshire.

Ph 302.05 Reciprocity Application Procedure. Once the application has been received in the board office the candidate shall be provided with copies of the "Pharmacy Law Handbook" and rules.

Ph 302.06 Reciprocity Application Time Limitation. Candidates who fail to complete and pass the jurisprudence examination, as required by Ph 302.04(j), within 90 days after the candidate's application is received at the board office shall have their applications denied, but fees shall be retained by the board. If a candidate wishes to re-apply for New Hampshire licensure, a new application containing updated information shall be filed with the board.

Ph 302.07 Jurisprudence Examination Required Scores and Fees.

(a) To successfully complete the examination required by Ph 302.04(j), the candidate shall, in the initial examination or any subsequent re-examination, obtain a score of not less than 75.

(b) The candidate shall pay the prescribed fee of \$185.

Ph 302.08 Jurisprudence Re-Examination Notice and Election.

(a) Any candidate who has failed to attain the minimum score in the jurisprudence section as required by Ph 302.07, shall notify the board whether he or she elects to be re-examined.

(b) Any re-examination permitted by this section shall be administered on a date and at a time convenient to the candidate and the board, but no later than 60 days after the date of notification that the candidate failed to attain the minimum score as required by Ph 302.07.

(c) Any candidate for re-examination of the jurisprudence examination shall remit the prescribed fee of \$185 prior to being re-examined.

Ph 302.09 Reciprocity License Issuance or Denial.

(a) If a candidate timely files an application, complete in all respects and meeting the requirements of Ph 302, and demonstrate the fulfillment of the requirements of these rules and RSA 318, the board shall issue a license to practice pharmacy.

(b) In the event a candidate for a reciprocity license to practice pharmacy in New Hampshire fails to meet the requirements of these rules or RSA 318, or both, the board shall deliver to the candidate a written denial of the application, specifying in detail each requirement which the candidate failed to meet, and how the candidate is deficient.

Ph 302.10 Certification of Scores/Licensure. Upon written request of the licensee, the board shall certify scores attained by the licensee in all pharmacy examinations administered by the board or that the licensee is duly licensed to practice the profession of pharmacy in New Hampshire. The written request shall contain the complete name and license number, if any, of the licensee.

PART Ph 303 PHARMACY PERMIT OPTIONS

Ph 303.01 Licensing the Entire Store Area.

(a) The pharmacy shall include the prescription department and all other retail sections of the store.

(b) The entire pharmacy shall be equipped with a functional alarm system to prevent entry when the pharmacy is not open to the public, according to Ph 702.04.

(c) The prescription department shall not be closed while the balance of the establishment remains open.

(d) A licensed pharmacist shall be on duty at all times when the pharmacy is open to the public.

Ph 303.02 Licensing Only the Prescription Department.

(a) The pharmacy shall include only the prescription department where drugs, chemicals, medicines, prescriptions are stored, compounded and dispensed. This area shall not include the other retail sections of the store the principle business of which is not the practice of pharmacy.

(b) The prescription department described in (a), above, shall be equipped with a functional alarm system to prevent entry when the pharmacy is not open to the public according to Ph 702.04.

(c) The prescription department may be closed while the remainder of the business establishment remains open to the public. During such periods, the pharmacy shall comply with Ph 702.04.

(d) A licensed pharmacist shall be on duty at all times when the prescription department is open to the public and during any absences by the pharmacist, the prescription department shall be secured except as is provided in Ph 704.01(b).

(e) Whenever the prescription department is closed, a sign indicating that there is no pharmacist on duty shall be conspicuously displayed in the pharmacy area. Such sign shall be composed of 3" lettering.

(f) Whenever the pharmacy is closed, prescriptions may be left via a mail slot which falls directly into the pharmacy area.

(g) The prescription mail slot:

(1) Shall be constructed so as to accept only a written or typed prescription or a notation of the prescription number for refills;

(2) Shall be no larger than 8" X 1" and designed so that prescriptions or notations, once deposited, cannot be retrieved by hand or by mechanical means; and

(3) Shall be constructed so as to deliver these prescriptions or notations directly into the prescription area for access by the pharmacist only so that they are not visible to the general public.

(h) No prescription, new or refill, shall be left with or accepted by clerks, pharmacy technicians as defined in RSA 318:1, XI-a or pharmacy interns as provided in RSA 318:42, IX when the prescription department is closed except as is provided in Ph 704.01(b).

(i) No finished prescriptions shall be left outside of the pharmacy area prescription department for pick-up when the prescription department is closed.

(j) No telephone prescriptions, new or refill, shall be accepted by clerks, pharmacy technicians or pharmacy interns when the prescription department is closed except as is provided in Ph 704.01(b).

(k) All drug order deliveries containing prescription drugs shall be delivered only when the prescription department is open and/or a licensed pharmacist is on the premises in order to secure such drug orders.

(l) A barrier preventing access to the prescription department by the public, shall be erected pursuant to the security requirements of Ph 702.04.

(m) The pharmacist-in-charge shall be in possession and control of keys to the prescription department. Only New Hampshire licensed pharmacists employed by the pharmacy may be designated by the pharmacist-in-charge to have keys and a list of these individuals shall be communicated to the board of pharmacy in writing whenever changes occur.

(n) All prescription departments licensed under this section shall be so equipped with a physical barrier from floor to ceiling capable of being locked and alarmed, separate from the rest of the store, to be utilized when the prescription department is not opened to the public.

Ph 303.03 Conversion of Pharmacy Permit. Conversion from licensure of the entire store to licensure of only the prescription department shall require:

(a) Plans be submitted to the board before renovations begin; and

(b) Once completed, an AMEND-A-PERMIT form, Ph A-4, pursuant to Ph 306.05, together with the prescribed fee of \$150., shall be submitted to the board. This form shall be processed and a new pharmacy permit issued before the pharmacy department may open different hours from the remainder of the establishment.

PART Ph 304 ORIGINAL PHARMACY PERMIT APPLICATION

Ph 304.01 Obtaining and Filing a Permit Application. Applications for a permit to operate a pharmacy in New Hampshire may be obtained from, and shall be filed at, the board office, identified in Ph 103.03.

Ph 304.02 Application Contents.

(a) The applicant for a permit to operate a pharmacy in New Hampshire, shall supply on form Ph A -3, at least the following information:

- (1) Type of pharmacy;
- (2) Name and home address of licensing pharmacist;
- (3) Name of pharmacy;
- (4) Identification of ownership,
- (5) Pharmacy operation hours;
- (6) Name, license number, hours worked for all pharmacists employed;
- (7) Approximate value of prescription drug inventory;
- (8) List of persons having keys/access to the pharmacy; and
- (9) Signature of the pharmacist-in-charge and date signed.

(b) The applicant shall also submit scale drawings of the pharmacy, detailing usage of all space.

(c) The applicant shall supplement the application with any certificates, affidavits, plans, documents, or other information sufficient to show full compliance with all of the requirements of part Ph 304.

(d) If the applicant is a corporation, or if the pharmacy will be operated under a corporate name, the applicant shall submit a certificate from the secretary of state attesting to the documents creating the corporate person and any amendment(s) thereof to the certificate of incorporation, or authorizing it to do business in the state of New Hampshire under the corporate name.

(e) The application shall be filed with the prescribed fee of \$500.

PART Ph 305 ORIGINAL PERMIT PROCEDURE

Ph 305.01 Original Permit Conference.

(a) In addition to all requirements set forth in the statutes and elsewhere in this chapter, each applicant applying for a permit to operate a pharmacy in New Hampshire shall appear before the board for an informal conference to review the responsibilities of the pharmacist-in-charge and to determine if, in the opinion of the board, issuance of the permit would be in the best interest of public health and welfare.

(b) If the owner is not the pharmacist-in-charge, then the owner or an officer of the corporation, or the district manager, as well as the anticipated pharmacist-in-charge shall appear before the board.

Ph 305.02 Site Inspection for Original Permit.

(a) Following the applicant's conference, the proposed site shall be inspected by one or more board members or compliance inspectors to determine if the premises are secure and suitable, according to the provisions of Ph 702, for the operation of a pharmacy and that the required professional library material, according to Ph 702.07 (7) (8), is available.

(b) Within the 60 day period after the issuance of the temporary permit as required by Ph 305.03, an inspector or a board member or both shall inspect the pharmacy. The full operation of the pharmacy shall be examined for compliance with federal and state statutes and rules governing the practice of pharmacy to ensure public protection.

Ph 305.03 Issuance and Denial of Original Permit.

(a) Providing that, the premises are suitable, according to Ph 305.02 (a), for the operation of a pharmacy and the applicant has met all other requirements of these rules and RSA 318, the applicant shall be granted a temporary permit which shall expire in 60 days. The temporary permit shall authorize the operation of a pharmacy only in the location and only under the name specified in the permit and shall authorize the pharmacist-in-charge to buy, possess and dispense prescription drugs, chemicals and pharmaceuticals.

(b) If an applicant files an application, complete in all respects and demonstrates the fulfillment of all of the requirements of these rules and RSA 318, the board shall issue a permit which shall authorize the operation of a pharmacy only in the location, and only under the name, specified in the permit.

(c) After consideration of the application and the report of the primary site inspection, the board shall notify the applicant in writing of all deficiencies in the application which, in the absence of correction, shall result in the denial of the application. The applicant shall, within 20 days of the date of the notice of deficiency, deliver to the board either documents evidencing the correction of those deficiencies, or a written request for an appeal before the board. In the absence of a timely filing of either documentation or a request for an appeal, the application shall, without further action or notice by the board, be denied effective as of the expiration of 20 days after the date of the notification of deficiency.

PART Ph 306 PERMITS - CHANGES IN SUPPORTING DATA

Ph 306.01 Pharmacy Ownership Transfer. A transfer of ownership shall include any of the following:

- (a) The sale of the pharmacy;
- (b) The addition or deletion of one or more partners in a partnership;
- (c) The death of a singular owner; or

(d) In a publicly traded, multi-tiered corporation, the lowest tier of the corporate structure doing business as a pharmacy in the State of New Hampshire.

Ph 306.02 Reporting Changes. The person to whom a permit to operate a pharmacy in New Hampshire has been issued shall, within 15 days of that person's discovery of a change in any of the data contained in the application for an original or renewal permit, report that change to the board in writing. An original permit application form shall be filed in addition to the written notice when the location or ownership of the pharmacy is changed. An amended application form shall be filed in addition to the written notice when the pharmacist-in-charge or the name of the pharmacy or both is changed.

Ph 306.03 Change in Pharmacy Name or Location - Prohibited. No person shall operate a pharmacy under a name, or at a location, different from the name and location contained in the permit issued pursuant to Ph 304, or an amendment of that permit issued pursuant to Ph 305.

Ph 306.04 Renovations. Plans for any renovation at any time after an original permit is issued shall be filed with the board for review and approval before proceeding with such changes.

Ph 306.05 Amend Permit Application Contents and Where Filed.

(a) Each applicant for amending a pharmacy permit for the purpose of a change of pharmacist-in-charge, a pharmacy name change or a licensed area change shall make application on an Amend-A-Pharmacy Form Ph A-4.

(b) Applicants filing a form Ph A-4 shall supply at least the following:

- (1) The type of change requested;
- (2) The names of the prior and current/new pharmacist-in-charge;
- (3) The names of pharmacist(s) on staff;
- (4) The date changes will be effective;

- (5) The pharmacy's hours;
- (6) A record of convictions or any findings of violations of pharmacy or drug related law against any individual or corporation named in this application; and
- (7) Signature of the pharmacist-in-charge and date signed.

(c) The application shall be filed at the board office identified in Ph 103.03 and submitted with the prescribed fee of \$150.

Ph 306.06 Issuance and Denial of Amended Permits.

(a) If a registrant shall file an application, complete in all respects, and shall have demonstrated the fulfillment of all of the requirements of this part, the board shall issue an amended permit. Upon receipt of this new permit, the licensee's existing permit shall be returned to the board office identified in Ph 103.03. Upon receipt of that amended permit the registrant shall operate the pharmacy under that amended permit.

(b) After consideration of the application, the board shall notify the licensee in writing of any deficiencies in the application. The licensee shall, within 20 days of the notice of deficiency, deliver to the board either documentation evidencing the correction of those deficiencies, or file a written request for an appeal before the board. In the absence of a timely filing of either that documentation or a request for appeal, the application, shall, without further action or notice by the board, be denied effective as of the expiration of 20 days after the date of the notification of deficiency.

PART Ph 307 RENEWAL AND REPLACEMENT PERMITS

Ph 307.01 Renewal Permits Required. The person to whom a permit to operate a pharmacy in New Hampshire has been issued shall renew that permit whenever any of the following occur:

- (a) The pharmacist-in-charge terminates his or her status as the pharmacist-in-charge;
- (b) The license of the pharmacist-in-charge is suspended or revoked;
- (c) Ownership of the pharmacy for which the permit was issued is changed;
- (d) The location of the pharmacy is changed; or
- (e) The calendar year ends.

Ph 307.02 Renewal Application Where Obtained and Filed. Applications for the renewal of a permit to operate a pharmacy in New Hampshire may be obtained from, and shall be filed at the board office.

Ph 307.03 Renewal Application Contents and When Filed.

(a) Applications for renewal of a permit to operate a pharmacy in New Hampshire shall consist of the prescribed form Ph A-3 as specified in Ph 304.02 and the prescribed fee of \$250.

(b) Renewal applications shall be filed with the board in accordance with the following schedule:

(1) When the renewal is required pursuant to Ph 307.01 (a) through (d), not later than 60 days prior to the date upon which those causes shall be effective, or as soon thereafter as the licensee discovers, or with reasonable diligence, should have discovered, the existence of the cause; or

(2) When the renewal is required pursuant to Ph 307.01 (e), not later than the 15th day of December of each year.

Ph 307.04 Renewal Application Deficiencies. The board shall notify the applicant in writing as to how the application for renewal is deficient. The applicant may, within 10 days after the date of the notice of deficiency, correct the deficiency or file with the board a written request for an appeal.

Ph 307.05 Issuance and Denial of Renewal Permit.

(a) If an applicant shall timely file an application, complete in all respects, and shall demonstrate the fulfillment of all the requirements of these rules and RSA 318, the board shall issue a renewal permit.

(b) An application which continues to fail to meet the requirements of these rules and RSA 318 shall, after the notice and opportunity for hearing provided in Ph 307.04, be denied.

Ph 307.06 Replacement Permit Application and Contents.

(a) The holder of a current permit to operate a pharmacy in New Hampshire, whose permit has been lost or destroyed shall apply for a replacement permit within 15 days after the date the licensee discovers, or with reasonable diligence, should have discovered, the loss or destruction of the permit. There shall be no form prescribed for an application for a replacement permit.

(b) The request for a replacement permit shall:

- (1) Be in writing;
- (2) Contain the number of the current permit held by the applicant, if known;
- (3) Be accompanied by the remains, if any, of the permit for which a replacement is sought;
- (4) Be accompanied by the prescribed fee of \$50; and
- (5) Be filed at the board office.

PART Ph 308 REVOCATION AND SUSPENSION

Ph 308.01 Effect of Revocation.

(a) The revocation of a pharmacy permit shall permanently withdraw the authority to operate a pharmacy in New Hampshire.

(b) A subsequent permit may be obtained only by:

- (1) Complying with all of the requirements of RSA 318 and these rules regarding the original licensing of pharmacies;
- (2) Paying all penalties assessed in connection with the cause for revocation; and

- (3) By demonstrating that the cause for revocation does not exist at the time of the subsequent application.

Ph 308.02 Effect of Suspension.

- (a) The suspension of a pharmacy permit shall temporarily withdraw the authority to operate a pharmacy in New Hampshire until the time specified in the order of suspension.
- (b) The authority to operate a pharmacy in New Hampshire shall be recovered only by;
 - (1) Complying with all of the requirements specified in the order of suspension;
 - (2) Complying with all of the requirements of RSA 318 and these rules regarding the renewal of a pharmacy permit; and
 - (3) Paying all penalties assessed in connection with the cause for suspension.

Ph 308.03 Voluntary Surrender When Permitted.

- (a) Any person holding a pharmacy permit may voluntarily return that permit to the board.
- (b) The return of such permit shall be accompanied by the licensee's signed, written statement as to why the permit is being voluntarily returned to the board.
- (c) The voluntary surrender of a permit to operate a pharmacy in New Hampshire shall serve to withdraw the authority for the licensee to operate that pharmacy in New Hampshire.
- (d) Voluntary surrender of a permit to operate a pharmacy in New Hampshire shall not be permitted if there exists, at the time the permit is presented to the board, any cause for involuntary revocation or suspension of the licensee's permit to operate a pharmacy, unless the licensee presenting the permit shall state in writing that the voluntarily surrendered permit is in lieu of proceedings for the involuntary revocation or suspension of the permit to operate a pharmacy in New Hampshire.

Ph 308.04 Hearing. Except as authorized by statute or these rules, a permittee to operate a pharmacy in New Hampshire shall not be disciplined except after notice and opportunity for hearing provided by Ph 200.

Ph 308.05 Other Licensing Fees. The annual licensing fee for federally funded clinics under the direction of the department of health and human services shall be \$150 and for drug abuse treatment centers shall be \$150.

Ph 308.06 Other Examination Fees. - REPEALED

PART Ph 309 STANDARDS OF PRACTICE FOR MANUFACTURERS, WHOLESALERS AND DISTRIBUTORS

Ph 309.01 License Required.

- (a) No person shall manufacture or act as a wholesale distributor of prescription drugs or prescription devices without first obtaining a license to do so from the board according to RSA 318:51-a. No license shall be issued or renewed for a manufacturer or wholesale drug distributor unless the same

shall be operated in a manner prescribed by law and according to the rules adopted by the board of pharmacy with respect thereto.

(b) Separate licenses shall be required for each manufacturing and distribution site owned or operated by a manufacturer or wholesale distributor. Provided however, that an agent or employee of any licensed manufacturer or wholesale distributor shall not be required to be licensed under this section and may lawfully possess prescription drugs and devices if he is acting in the usual course of his business or employment.

(c) The board shall provide, on an annual basis, a license renewal form to all licensed manufacturers and wholesale distributors of prescription drugs and devices.

(d) The prescribed fee for original and annual renewal licenses for manufacturers and wholesale distributors of prescription drugs and devices shall be \$250.

Ph 309.02 Obtaining and Filing a License Application. Applications for licensure of manufacturers, wholesalers and distributors may be obtained from, and shall be filed at, the board office, identified in Ph 103.03.

Ph 309.03 Application Contents. The applicant for licensure shall supply, on form Ph A-4, at least the following information:

- (a) Name of the company;
- (b) The address of the actual location where manufacturing, wholesaling and distribution occurs;
- (c) Identification of ownership; and
- (d) Name and address of the person responsible for licensing.

Ph 309.04 Storage Conditions. All facilities at which prescription drugs are repackaged, wholesaled, stored, held, sold, offered for sale, exposed for sale, or kept for sale shall provide storage areas that ensure proper lighting, ventilation, temperature, sanitation, humidity, equipment, and security conditions. All prescription drugs or chemicals shall be stored at appropriate temperatures per label requirements or in compliance with the latest edition of the official United States Pharmacopeia (USP) compendium requirements to help ensure that the identity, strength, quality, and purity of the products are not affected. If no temperature requirements are listed, prescription drugs may be stored at room temperature in compliance with U.S.P. definition for room temperature. A separate storage section shall be provided for prescription drugs that are deteriorated, outdated, misbranded, or otherwise adulterated.

Ph 309.05 Facilities.

(a) All buildings in which prescription drugs are wholesaled, repackaged, stored, held, sold, offered for sale, exposed for sale, or kept for sale shall be of suitable size, construction, and location to facilitate cleaning and maintenance.

(b) Buildings shall meet all applicable federal, state, and local standards. A facility shall not be located in a residence. All facilities shall be located in an area that is commercially zoned.

(c) A wholesale drug distribution facility shall notify the local police department or other appropriate law enforcement agency that it is a distributor of prescription drug products and controlled substances.

Ph 309.06 Security.

(a) Each wholesale drug distribution center shall be equipped with an internal alarm system to detect entry after hours. The alarm system shall be of the type that transmits a signal directly to a central station protection company, to a local or state police agency that has a legal duty to respond, a 24 hour control station operated by the wholesale drug distributor.

(b) Manufacturers and wholesale drug distributors shall ensure that all access from outside their premises is secure. This shall include, but not be limited to, the installation of adequate lighting at the outside perimeter of the premises.

(c) Internal security policies shall be developed to provide protection against theft by personnel.

Ph 309.07 Recordkeeping.

(a) Inventories and other records of transactions regarding the receipt and disposition of prescription drugs shall be maintained and made available for inspection by the board's inspectors for a period of 2 years.

(b) Records may be kept at a central location rather than at each distribution center, but records shall be made available for inspection within 72 hours of request by the board's inspectors.

Ph 309.08 Inspections.

(a) Inspections shall be performed by the board's inspectors and be conducted at the request of the board.

(b) Inspections shall be conducted during normal business hours, and notification of inspections shall be given no less than 48 hours in advance.

(c) Information that is considered to contain trade secrets or which might be proprietary in nature shall be protected from public disclosure.

Ph 309.09 Written Policies and Procedures.

(a) Written policies and procedures shall be developed by management personnel to assure that the manufacturer and wholesale drug distributor prepares for, protects against, and handles crisis situations that affect the security or operation of the facility. Such crises may include fires, floods, or other natural disasters, and situations of local, state or national emergency.

(b) Written policies and procedures described in (a) above shall also provide for:

(1) The management and correction of all errors or inaccuracies in inventories;

(2) The assurance that any outdated stock, or any stock with an expiration date that, in the wholesale drug distributor's view, does not allow sufficient time for repacking or resale, shall be prepared for return to the manufacturer or otherwise destroyed; and

(3) The control over the shipping and receiving of all stock within the operation.

(c) A copy of the policies and procedures, or sections thereof, shall be made available to the board upon request.

Ph 309.10 Returned Goods. A wholesale operation shall maintain a procedure for the proper handling and disposal of returned goods.

Ph 309.11 Handling Recalls.

(a) A wholesale operation shall maintain a written policy for handling recalls and withdrawals for products.

(b) Policies required by (a) above shall cover all recalls and withdrawals of prescription drug products due to:

- (1) Any voluntary action on the part of the manufacturer;
- (2) The direction of the Food and Drug Administration, or any other federal, state or local governmental agency; and
- (3) Replacement of existing merchandise with an improved product or new package design.

Ph 309.12 Responsibility for Operation. A wholesale drug distribution operation shall maintain a list of principals and persons in charge including officers, directors, or primary stockholders and their qualifications.

Ph 309.13 Compliance with State and Federal Law.

(a) All manufacturers, wholesalers and distributors shall comply with all applicable state and federal laws and regulations.

(b) All manufacturers, wholesalers and distributors, doing business in New Hampshire, shall, before shipping or distributing any prescription drug, verify that the recipient is properly licensed to receive and possess such drugs.

(c) All manufacturers, wholesalers and distributors, licensed and doing business in the state of New Hampshire, shall not provide unsolicited controlled drug samples to licensed practitioners.

(d) A manufacturers license shall allow for the direct wholesaling or distribution of such drugs to other licensed or authorized recipients.

(e) A duly authorized agent of a manufacturer, wholesaler or distributor licensed in this state, may possess and distribute potent or prescription drugs to individuals who may lawfully possess such drugs as may be necessary to further the licensed activity of the manufacturer, wholesaler or distributor.

(f) Indirect sale or distribution shall include, but not be limited to:

- (1) Solicitation, in this state, by manufacturers, wholesalers or distributors sales representatives;
- (2) Telephone solicitations to customers located in this state by manufacturers, wholesalers or distributors sales representatives;
- (3) Solicitation of customers located in this state by mail or by the use of media advertising which has a significant circulation in the state of New Hampshire.

Ph 309.14 Violations.

(a) No manufacturer or wholesaler shall distribute prescription drugs directly to a consumer or a patient, or operate in such a manner as to endanger the public health.

(b) Any person who manufacturers, wholesales, or otherwise distributes prescription drugs, according to RSA 318:51-a and the provisions of Ph 309, shall be subject to disciplinary action as provided in RSA 318:29.

CHAPTER Ph 400 CONTINUED STATUS

PART Ph 401 RENEWAL AND REPLACEMENT LICENSES

Ph 401.01 Obtaining and Filing Renewal Applications. Applications for the renewal of a license to practice pharmacy in New Hampshire may be obtained from, and shall be filed at, the board office.

Ph 401.02 Renewal Application Contents and Filing Deadline.

(a) Applications for renewal of a license to practice pharmacy in New Hampshire under RSA 318 shall be made on a Pharmacist Licensure Renewal Form Ph A-2.

(b) Each applicant shall provide the following on Form Ph A-2 regarding himself/herself:

- (1) Name, residence address, home telephone number, original pharmacy license, and date of birth;
- (2) Name of current employer, address of employment site, hours worked per week;
- (3) Record of charges, convictions, indictments for violations of Federal, State, local drug or pharmacy related law or regulations;
- (4) Current licensure in other states;
- (5) Report of continuing education; and
- (6) Applicant's signature and date.

(c) The application and the prescribed fee of \$100 shall be filed with the board no later than the 15th day of December each year. Each licensee shall obtain and file his or her application for license renewal prior to this date.

Ph 401.03 Renewal Application Deficiencies. Within 5 days of receipt at the board office, the board shall notify the applicant in writing if the renewal application is deficient. The applicant may then correct the deficiency or file with the board a written request for a hearing before the board.

Ph 401.04 Renewal License Issuance and Denial.

(a) If an applicant timely files an application, complete in all respects, and demonstrates the fulfillment of all the requirements of these rules and RSA 318, the board shall issue a renewal license to practice pharmacy.

(b) An application failing to meet the requirements of these rules or RSA 318, or both, shall, after the notice and opportunity for hearing provided in Ph 401.03, be denied.

Ph 401.05 Duplicate/Replacement Original Certificate of Licensure or Renewal License - Issuance.

(a) If for an original certificate of licensure the applicant shall:

- (1) Submit a written request, signed by the pharmacist, to the board for replacement; and
- (2) Provide payment of the prescribed fee which shall be \$50.

(b) If for an annual renewal license the applicant shall:

- (1) Submit a written request, signed by the pharmacist, to the board for a duplicate or replacement; and
- (2) No fee shall be assessed for a duplicate or replacement renewal license.

Ph 401.06 Reinstatement. A pharmacist whose license to practice pharmacy in this state has been suspended, revoked, voluntarily surrendered or allowed to lapse for a period of 12 months or more shall be subject to the following requirements:

(a) File a reinstatement application with this board which shall include at least the following:

- (1) Name, address and telephone number of the applicant;
- (2) Date of birth; and
- (3) Current employment information.

(b) Pay the reinstatement fee of \$200.

(c) Pay all yearly renewal fees in arrears.

(d) Submit original certificates of attendance/participation in accredited/approved continuing pharmaceutical education courses/programs for a minimum of 15 hours, of which at least 5 hours shall be earned in a didactic setting. All such continuing education shall have been earned in the period 12 months immediately preceding the date of application for reinstatement.

(e) Successfully complete the jurisprudence examination as specified in Ph 302.07(a).

(f) If the pharmacist has not held a license to practice pharmacy in this state for a period of 2 years or more, the applicant shall provide:

- (1) Notarized affidavit(s) documenting the pharmacist's pharmacy experience during the 2 years immediately preceding the date of his/her application for reinstatement; and
- (2) Proof of status of licensure in all states that the pharmacist has been licensed in.

(g) If the pharmacist has not held a license to practice pharmacy in this state for a period of 5 years or more and has not practiced pharmacy in any other state, the board shall consider the additional requirement for the completion of a period of pharmacy practice internship prior to reinstatement.

Ph 401.07 Gold Certificates.

(a) The board of pharmacy shall issue a gold certificate to any pharmacist who has been regularly licensed as a pharmacist for 50 consecutive years.

(b) Gold certificates shall be distinctive in coloration and text from other pharmacist licenses issued by the board, and shall be designed to appropriately recognize each recipient pharmacist for his/her half-century of professional practice.

(c) A gold certificate shall be a one-time issuance of honorary nature and confer no right to practice pharmacy upon the recipient.

(d) The awarding of gold certificates shall be made by the board of pharmacy without charge to the recipient.

PART Ph 402 DISCIPLINARY MATTERS

Ph 402.01 Effect of Revocation.

(a) The revocation of a pharmacist license shall permanently withdraw the authority to practice pharmacy in New Hampshire.

(b) A subsequent license may be obtained only by:

- (1) Complying with all of the requirements of RSA 318 and these rules regarding the original licensing of pharmacists;
- (2) Paying all penalties assessed in connection with the cause for revocation; and
- (3) Demonstrating that the cause for revocation does not exist at the time of the subsequent application.

Ph 402.02 Effect of Suspension.

(a) The suspension of a pharmacist license shall temporarily withdraw the authority to practice pharmacy in New Hampshire until the time specified in the order of suspension.

(b) The authority to practice pharmacy in New Hampshire shall be recovered only by:

- (1) Complying with all of the requirements specified in the order of suspension;
- (2) Complying with all of the requirements of RSA 318 and these rules regarding the renewal of a license to practice pharmacy in New Hampshire; and
- (3) Paying all penalties assessed in connection with the cause for suspension.

Ph 402.03 Voluntary Surrender of License.

(a) Any person holding a pharmacist license may voluntarily surrender that license by returning it to the board accompanied by a signed letter stating that the pharmacist intends to permanently surrender his or her license.

(b) The surrender shall be effective upon receipt and shall immediately preclude the pharmacist from practicing pharmacy in New Hampshire.

(c) A voluntary license surrender, standing alone, shall not prevent the pharmacist from subsequently reapplying for a license.

(d) The voluntary surrender of a license shall have no effect upon the board's authority to:

(1) Investigate violations of the pharmacy laws or the rules of the board by a person licensed at the time the alleged violation occurred; or

(2) Impose disciplinary sanctions based on past conduct which could affect the ability of the former licensee to reapply for a license at a later date.

(e) A voluntary license surrender during the pendency of a disciplinary proceeding shall be recorded in the board's files as "surrendered during disciplinary proceeding."

(f) Nothing in this section shall prohibit the board and a licensee from entering into a settlement agreement or a consent decree relative to any alleged violation of the pharmacy laws or the rules of the board.

Ph 402.04 Hearing. Except as authorized by statute or these rules, a licensee shall not be disciplined except after notice and opportunity for hearing.

PART Ph 403 CONTINUING EDUCATION REQUIREMENTS

Ph 403.01 Definitions.

(a) "Accredited programs/courses" means continuing education sponsored by providers which are approved by the American Council on Pharmaceutical Education (ACPE) or the Canadian Council on Continuing Education in Pharmacy (CCCEP).

(b) "Board approved programs/courses" means continuing education which has been reviewed and recommended by the continuing education advisory council and approved by the board of pharmacy or continuing education programs approved by a Canadian provincial or territorial pharmacy licensing authority.

(c) "AMA category I programs" means all programs accepted by the American Medical Association in category I.

(d) "Continuing education" means accredited or approved post-licensure pharmacy education designed to maintain professional competence in the practice of pharmacy, improve professional skills, and preserve pharmaceutical standards for the purpose of protecting the health and welfare of the citizens in the state of New Hampshire. Continuing education includes study in one or more of the general areas of the properties and actions of drugs and dosage forms, etiology, characteristics and therapeutics of the disease state, socio-economic and legal aspects of health care.

(e) "Continuing education advisory council (CEAC)" means a group of individuals appointed by the board of pharmacy to serve in an advisory capacity on continuing education.

(f) "Continuing education unit (CEU)" means 10 contact hours of participation in accredited or board approved continuing education courses/programs.

(g) "Certificate of accredited/approved CEU's" means a document, issued to a particular pharmacist by an accredited or approved provider certifying that the pharmacist has satisfactorily

completed a specified number of CEU's. Such certificates include a unique program identification number issued by the accrediting/approving provider.

(h) "In-state approved provider" means an individual, institution, organization, association, corporation or agency located in the state of New Hampshire in no manner affiliated with any manufacturer or distributor of supplies or services used in the practice of pharmacy, who is approved by the board of pharmacy to provide continuing pharmacy education according to 403.13.

Ph 403.02 Renewal Requirements.

(a) The board of pharmacy shall not issue licensure renewals unless the pharmacist indicates on the renewal application, and under penalty of unsworn falsification, that he/she has completed the minimum required hours of accredited/approved continuing pharmaceutical education courses/programs according to Ph 403.02(d). An incomplete renewal application shall be returned to the applicant.

(b) Continuing education shall be required of all licensed, active or inactive pharmacists who apply for license renewal.

(c) Pharmacists submitting applications for the first annual licensure renewal after initial New Hampshire licensure shall be exempt from the continuing education requirements.

(d) All pharmacists licensed in New Hampshire shall acquire 1.5 CEU's during the 12 months immediately preceding the license renewal date of January 1st. At least 0.5 CEU's shall be earned in a didactic setting.

(e) Continuing education credits shall not be recognized for any repeat program attended or completed. Repeat programs shall be identified as any program, didactic or correspondence, which carries the same ACPE, CME or any board of pharmacy program identification number.

(f) The pharmacist shall retain all certificates and/or other documented evidence of participation in an approved/accredited continuing education program/course for a period of at least 3 years. Such documentation shall be made available to the board for random audit and/or verification purposes.

(g) Not less than 10% of the registrants shall be randomly selected each year by the board for determinations of compliance with Ph 403.02.

Ph 403.03 Excess CEU's. Excess CEU's earned in one licensure period shall not be carried forward into the new licensure period for the purpose of fulfilling that year's continuing education prerequisite for licensure renewal.

Ph 403.04 CEU's from Other States. The board of pharmacy shall accept comparable continuing education units which have been approved by other boards of pharmacy provided they meet or exceed the requirements as set forth in Ph 403.

Ph 403.05 Credit for Instructors of Continuing Education.

(a) Any pharmacist, whose primary responsibility is not the education of health professionals, who leads, instructs or lectures to groups of nurses, physicians, pharmacists or others on pharmacy related topics in organized continuing education or in-service programs, shall be granted continuing education credit for such time expended during actual presentation.

(b) Any pharmacist whose primary responsibility is the education of health professionals shall be granted continuing education credit only for time expended in leading, instructing, or lecturing to groups of physicians, pharmacists, nurses or others on pharmacy-related topics outside his/her formal course responsibilities in a learning institution.

(c) Credit for presentation of in-service training programs or other lectures shall be granted only once for any given program or lecture.

(d) A maximum of 4 hours in this category may be applied toward fulfilling the total continuing education yearly requirements. However, these hours shall not be considered in fulfilling the didactic requirements as set forth in Ph 403.02(d).

Ph 403.06 Postgraduate Pharmacy Curricula.

(a) A pharmacist who matriculates in a postgraduate pharmacy curriculum or post graduate pharmacy program shall be awarded CEU's for satisfactory completion of each course within said curriculum or program.

(b) The course work for which CEU credit shall given pursuant to (a) above shall provide instruction in one or more of the following areas of study:

- (1) Pharmacy;
- (2) Pharmaceutical calculations;
- (3) Pharmaceutical chemistry;
- (4) Pharmacology;
- (5) Therapeutics;
- (6) Pharmacy management;
- (7) Pharmaceutical jurisprudence; or
- (8) Other course work related to the pharmaceutical sciences.

Ph 403.07 Audio/Visual Continuing Education.

(a) Continuing education credit may be claimed for the completion of home study audio and/or video cassette tape programs/courses, provided that such programs require the completion of a written exam by the pharmacist to be scored by the provider of such programs.

(b) Audio/visual continuing education programs, including satellite transmissions, which provide for group discussion and include a facilitator shall, be allowed as didactic programming.

Ph 403.08 Waiver. The board shall waive some or all of the continuing education requirements, for a period not to exceed one calendar year, for such hardships as illness or incapacity. Written request for waiver shall be submitted to the board for consideration.

Ph 403.09 Military Personnel. Military personnel or spouses shall not be exempt from the continuing education requirements, because correspondence programs/courses are available, but shall be exempt from the didactic requirement if assignment is in a foreign country.

Ph 403.10 Reinstatement. Any pharmacist desiring reinstatement of licensure shall show evidence of completion of at least 1.5 CEU's, according to Ph 403.02(d) and earned in the 12 months immediately preceding the date of application for reinstatement.

Ph 403.11 Penalty. Any pharmacist who alters, forges, or intentionally falsifies, or causes to be altered, forged, or falsified any information, documents, or records required to be kept or submitted by this rule shall be subject to disciplinary action under RSA 318:29,II. Falsification of records shall constitute misconduct.

Ph 403.12 In-State Approved Providers of Continuing Pharmacy Education.

(a) An individual, institution, organization, association, corporation or agency located in the state of New Hampshire desiring to be an in-state provider of continuing pharmacy education shall notify the board in writing subject to the criteria set forth in Ph 403.12 (d)(1)-(10).

(b) Approval of in-state providers shall be valid for a period of 2 years from date of approval after which time re-application shall be necessary.

(c) In-state providers who desire to become approved by the board shall demonstrate ability and willingness to offer quality continuing pharmacy education in a responsible manner and shall adhere to the provisions of (d), below.

(d) Providers shall comply with the following:

(1) The provider shall designate a responsible person for the administration of the continuing pharmacy education program and liaison with the CEAC and the board;

(2) Providers shall award continuing pharmacy education credit to successful participants in terms of CEU's;

(3) The provider shall maintain a list of successful participants for each program provided for a period of not less than 3 years;

(4) The list required by (3) above shall be made available to the CEAC and the board on request;

(5) The provider shall award to each successful participant a certificate containing at least the following information:

a. The name of the provider;

b. The completion date of the continuing education program;

c. The name of the participant;

d. The title of the program;

e. The number of CEU's the program has been assigned; and

f. The board of pharmacy program identification number;

(6) All programs shall be referenced as "didactic" or "correspondence" in nature;

(7) Providers shall present their participants with a statement of goals and objectives prior to each continuing pharmacy education program and involve their participants in identifying their own educational needs;

(8) Providers shall develop and employ evaluation techniques that will assess the effectiveness of the continuing pharmacy education offerings and the level of fulfillment of the stated objectives with the goal of continual improvements;

(9) Providers shall utilize an evaluation mechanism for the purpose of allowing each participant to assess his/her achievement of personal objectives; and

(10) Providers shall assign an identification number to every program presented according to the numbering system designated by the board of pharmacy.

(e) Continuing education programs presented by in-state approved providers shall not have to be submitted to the CEAC for review and approval by the board.

(f) In-state approved providers of continuing pharmacy education shall publicize programs and/or coursework by referencing endorsement by the board only as follows: "This program is approved by the New Hampshire Board of Pharmacy for _____ CEU's of continuing pharmacy education". Programs shall also be referenced as "didactic" or "correspondence" in nature.

(g) Board approval of in-state provider shall be revoked following notice and opportunity to be heard upon a finding that the provider has engaged in fraud or dishonesty or is no longer in compliance with one or more of the criteria of (d) above.

Ph 403.13 Continuing Education Advisory Council Membership.

(a) The advisory council shall consist of not less than 6, nor more than 10 members, at least one of whom shall be a member of the board.

(b) The term of appointment shall be for 3 years and shall be served until the expiration date or until a successor has been named. Should a vacancy occur, a successor shall be appointed to serve the unexpired term.

(c) The advisory council shall submit all recommendations to the board for its implementation and/or approval.

(d) It shall be the duty of the advisory council to:

(1) Elect from its membership a chairman and a secretary annually;

(2) Recommend to the board the standards and specifications required of programs/courses which might be acceptable for board approval in fulfilling continuing education requirements;

(3) Recommend programs which meet the standards and specifications adopted;

(4) Recommend the number of CEU's granted for the satisfactory completion of approved programs; and

(5) Provide such other assistance to the board necessary in the implementation and maintenance of the continuing education licensure renewal prerequisite.

(e) The advisory council shall meet a sufficient number of times annually to properly perform its functions.

(f) The advisory council quorum shall be equal to the majority of the council membership.

PART Ph 404 STANDARDS FOR COMPOUNDING AND DISPENSING STERILE PHARMACEUTICALS

Ph 404.01 Environment. Pharmacies engaged in the practice of compounding and dispensing of parenteral solutions shall have a designated area for the preparation of sterile products for dispensing which shall:

(a) Be in compliance with Federal Standard 209E, "Clean Room and Work Station Requirements," Controlled Environment, as approved by the Commission, Federal Supply Service, General Services Administration;

(b) Meet the standards for Class 100 HEPA filtered air such as a laminar air flow hood or clean room which shall:

(1) Have cleanable surfaces, walls and floors;

(2) Be ventilated in a manner not interfering with laminar air flow;

(3) Provide for an annual certification of the laminar air flow hood in compliance with Federal Standard 209D;

(4) Be arranged in such a manner that the laminar-flow hood is located in an area which is exposed to minimal traffic flow, and is separate from any area used for bulk storage of items not related to the compounding of parenteral solutions;

(5) Provide for sufficient space, well separated from the laminar-flow hood area, for the storage of bulk materials, equipment and waste materials;

(6) Include a sink with hot and cold running water within the parenteral solution compounding area; and

(7) Include a refrigerator and/or freezer of sufficient capacity to meet the storage requirements for all materials requiring refrigeration.

(c) Provide for the storage of bulk solutions and/or devices stored in designated areas outside of the licensed pharmacy area, provided that such areas have been authorized by the board, are secure and accessible only to authorized personnel.

(d) The annual certification in (b) (3) above, shall be retained for at least 3 years.

Ph 404.02 Laminar Hood. In all pharmacies preparing parenteral cytotoxic agents, all compounding shall be conducted within a certified Class II Type A or Class II Type B vertical laminar air flow hood with bag-in, bag-out design. The pharmacy shall ensure that contaminated air plenums that are under positive air pressure are leak tight.

Ph 404.03 Labelling. In addition to existing labelling requirements, parenteral product labels shall include:

- (a) The telephone number of the pharmacy;
- (b) The name and concentrations of all ingredients contained in the parenteral products including primary solution;
- (c) The instructions for storage and handling; and
- (d) A special label which states: "Chemotherapy-Dispose of Properly" for cytotoxic agents.

Ph 404.04 Records.

(a) Pharmacies engaged in the practice of compounding and dispensing of parenteral solutions shall have on the premises or readily accessible, a patient record for each patient being treated with parenteral therapy.

(b) In addition to existing recordkeeping requirements, the following records shall be maintained in the pharmacy:

- (1) A record of the furnishing of all prescriptions and medical supplies;
- (2) Information relevant to the patient's parenteral therapy, which shall include but not be limited to:
 - a. The patient's name, age, sex and address;
 - b. The telephone number of location where patient is receiving parenteral therapy;
 - c. The primary diagnosis related to need for prescribed therapy/secondary diagnosis;
 - d. A summary of the most recent hospitalization and/or previous history; and
 - e. Medication history, including current diet/medication regimen and drug/food allergies;
- (3) Progress notes documenting contact with the patient or physician relative to parenteral therapy; and
- (4) Laboratory data relevant to parenteral therapy.

Ph 404.05 Dress Code. Persons preparing cytotoxic agents shall wear gowns and gloves.

Ph 404.06 Consultation. Consultation by the pharmacist shall be available to the patient and/or primary caregiver concerning proper use of parenterals and related supplies furnished by the pharmacy.

Ph 404.07 Training. The managing pharmacist shall ensure all pharmacists engaging in compounding parenteral solutions shall have training or demonstrated previous training in the safe handling and compounding of parenteral solutions, including cytotoxic agents.

Ph 404.08 Policies and Procedures.

(a) Pharmacies providing parenteral services shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residues. The procedures shall include cleanup of spills and shall be in conformance with the requirements established by local public

health departments. The pharmacy shall ensure the return of such materials or shall communicate the proper destruction of such materials to the caregiver.

(b) Pharmacies engaged in the practice of compounding and dispensing parenteral solutions shall have written policies and procedures which describe the methods and approaches employed by the pharmacy in all areas of the pharmacy's parenteral therapy services.

Ph 404.09 Quality Assurance.

(a) The pharmacist-in-charge shall develop and maintain a quality assurance program that ensures a clean and sanitary environment for the preparation of sterile products and insures that the parenteral products that are produced are sterile. Documentation of such activities shall be available.

(b) The quality assurance program shall include at least the following:

- (1) Cleaning and sanitization of the parenteral medication preparation area;
- (2) Surveillance of parenteral solutions for microbiological contamination and actions taken in the event that testing for contamination proves positive;
- (3) Where bulk compounding of parenteral solutions is performed, the surveillance of parenteral solutions for microbiological contamination and pyrogens, and documentation of the results prior to dispensing to the patient;
- (4) Periodic documentation of the room and refrigerator temperature in which compounded parenteral products are stored;
- (5) Steps to be taken in the event of a drug recall; and
- (6) Written justification of expiration dates for compounded parenteral products.

Ph 404.10 Reference Library.

(a) Pharmacies engaged in the practice of compounding and dispensing parenteral solutions shall have current reference materials located in or immediately available to the pharmacy.

(b) In addition to Ph 702.07 (a)(7)(8), such reference materials shall include information on:

- (1) All drugs and chemicals used in parenteral therapy services; and
- (2) All parenteral therapy manufacturing, dispensing, distribution and counseling services provided.

Ph 404.11 Compounding Location. All sterile pharmaceutical solutions and products compounded and distributed by licensed facilities located out of state shall be in compliance with Ph 404.

PART Ph 405 STANDARDS OF PRACTICE FOR NUCLEAR/RADIOLOGIC PHARMACY

Ph 405.01 Purpose and Scope. The practice of nuclear pharmacy is hereby recognized as a specialty of pharmacy practice, regulated by the state board of pharmacy. As such, the following rules are included to address those areas specific or unique to this specialty practice. These rules shall supplement the rules/regulations of other state and federal agencies.

Ph 405.02 Definitions.

- (a) "Authentication of product history" means identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical or other drug.
- (b) "Nuclear pharmacy" means a pharmacy which provides radiopharmaceutical services.
- (c) "Practice of nuclear pharmacy" means a patient-oriented service that embodies the scientific knowledge and professional judgment required to improve and promote health through the assurance of the safe and efficacious use of radiopharmaceuticals and other drugs.
- (d) "Quality assurance procedures" means all activities necessary to guarantee the integrity of the process used to provide radiopharmaceutical services, including authentication of product history and maintenance of all records as required by the department of health and human services, bureau of radiological health.
- (e) "Quality control testing" means the performance of chemical, biological and physical tests on compounded radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals.
- (f) "Radiopharmaceutical" means any drug which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons. The term includes any nonradioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such substance, but does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides. The term also includes any biological product which is labeled with a radionuclide or intended solely to be labeled with a radionuclide.
- (g) "Radiopharmaceutical service" means the procurement, storage, handling, compounding, preparation, labeling, quality control testing, dispensing, distribution, transfer, record keeping and disposal of radiochemicals, radiopharmaceuticals and ancillary drugs.

Ph 405.03 General Requirements for Pharmacies Providing Radiopharmaceutical Services.

- (a) A permit to operate a pharmacy, which provides radiopharmaceutical services shall only be issued to a person who is, or who employs a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals and ancillary drugs shall be under the direct supervision of a qualified nuclear pharmacist, who shall be in personal attendance when the pharmacy is open for business. The pharmacist-in-charge shall be responsible for all operations of the pharmacy.
- (b) The nuclear pharmacist who licenses the pharmacy shall hold a current license issued by the board, and shall be either certified as a nuclear pharmacist by the board of pharmaceutical specialties or satisfy each of the following requirements:
 - (1) Meets minimal standards of training for status as authorized user of radioactive material, as specified by the department of health and human services, bureau of radiological health;
 - (2) Has successfully completed a minimum of 200 contact hours of instruction in nuclear pharmacy and the safe handling and use of radioactive materials from a nationally accredited college of pharmacy, or other training program recognized by the department of health and human services, bureau of radiological health;
 - (3) The 200 hours of instruction referenced in (2) above shall be apportioned as follows:

- a. Radiation physics and instrumentation, 85 hours;
- b. Radiation protection, 45 hours;
- c. Mathematics pertaining to the use and measurement of radioactivity, 20 hours;
- d. Radiation biology, 20 hours; and
- e. Radiopharmaceutical chemistry, 30 hours;

(4) Has attained a minimum of 500 hours of clinical/practical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist in, but not limited to, the following areas:

- a. Procuring radioactive materials;
- b. Compounding radiopharmaceuticals;
- c. Performing routine quality control procedures;
- d. Dispensing radiopharmaceuticals;
- e. Distributing radiopharmaceuticals;
- f. Implementing basic radiation protection procedures; and
- g. Consulting and educating the nuclear medicine community, patients, pharmacists, other health professionals, and the general public; and

(5) Has submitted an affidavit of experience and training to the board.

(c) The permit to operate a nuclear pharmacy shall be effective only so long as the pharmacy also holds a current license issued by the department of health and human services, bureau of radiological health. Copies of the bureau of radiological health inspection reports shall be available at the pharmacy for board inspection.

(d) Nuclear pharmacies shall have adequate space and equipment, commensurate with the scope of services required and provided and meeting minimal space requirements established for all pharmacies in the state.

(e) All pharmacies handling radiopharmaceuticals shall include, but not be limited to, the following areas:

- (1) Radiopharmaceutical preparation/dispensing area;
- (2) Radioactive material shipping/receiving area;
- (3) Radioactive material storage area; and
- (4) Radioactive waste decay area.

(f) The application for a permit to operate a nuclear pharmacy shall be the same as in Ph 304.01 and Ph 304.02.

(g) The nuclear pharmacy professional service area shall be secured from unauthorized personnel and shall be totally enclosed and lockable.

(h) Nuclear pharmacies shall maintain records of acquisition, inventory and disposition of all radioactive drugs and other radioactive materials in accordance with the board and the department of health and human services, bureau of radiological health statutes and rules.

(i) A radiopharmaceutical shall be dispensed only to a licensed practitioner authorized by the department of health and human services, bureau of radiological health to possess, use and administer such drug. A radiopharmaceutical shall be dispensed only upon receipt of a prescription or medication order from such licensed practitioner. Otherwise, a radiopharmaceutical may be transferred to a person who is authorized to possess and use such drug for non-clinical applications.

(j) A nuclear pharmacy, upon receiving an oral prescription order for a radiopharmaceutical, shall immediately have the prescription order reduced to writing, or recorded in a data processing system.

(k) The writing or record required by (i) above shall contain at least the following:

- (1) The name of the institution and prescriber, or prescribers' agent;
- (2) The date of dispensing and the calibration time of the radiopharmaceutical;
- (3) The name of the procedure;
- (4) The name of the radiopharmaceutical;
- (5) The dose or quantity of the radiopharmaceutical;
- (6) The serial number assigned to the order for the radiopharmaceutical;
- (7) Any specific instructions;
- (8) The initials of the person who received the order; and
- (9) The initials of the person who dispensed the order.

(l) Whenever an order is for a therapeutic or blood-product radiopharmaceutical, the patient's name shall be obtained and recorded prior to dispensing.

(m) The immediate outer container shield of a radiopharmaceutical to be dispensed shall be labeled with:

- (1) The name and address of the pharmacy;
- (2) The name of the prescriber;
- (3) The date of dispensing;
- (4) The serial number assigned to the order for the radiopharmaceutical;
- (5) The standard radiation symbol;
- (6) The words "Caution Radioactive Material";
- (7) The name of the procedure;
- (8) The radionuclide and chemical form;
- (9) The amount of radioactivity and the calibration date and time;

- (10) If a liquid, the volume;
- (11) If a solid, the number of items or weight;
- (12) If a gas, the number of ampules or vials;
- (13) Molybdenum 99 content to USP limits; and
- (14) The name of the patient or the words "Physician's Use Only" in the absence of a patient name.

(n) When the prescription is for a therapeutic or blood-product radiopharmaceutical, the patient name shall appear on the label. The requirements of this paragraph shall be met when the name of the patient is readily retrievable from the physician upon demand.

(o) The immediate inner container label of a radiopharmaceutical to be dispensed shall be labeled with:

- (1) The name of the pharmacy;
- (2) The standard radiation symbol;
- (3) The words "Caution Radioactive Material";
- (4) The identity of the radionuclide;
- (5) The chemical form;
- (6) The name of the procedure; and
- (7) Serial number of the radiopharmaceutical.

(p) When a radiopharmaceutical is dispensed under the authority of an investigational new drug application (IND), the nuclear pharmacy records shall include an investigator's protocol for the preparation of the radiopharmaceutical, and a letter from the manufacturer or sponsor indicating that the physician requesting the radiopharmaceutical is a qualified investigator.

(q) Each nuclear pharmacy shall have a current copy of the United States Pharmacopeia/National Formulary (USP/NF), USP-DI, and a current copy of state and federal rules and regulations governing the safe storage, handling, use, dispensing, transport and disposal of radiopharmaceuticals.

Ph 405.04 Minimum Equipment. The pharmacy shall have at least the following equipment:

- (a) A radionuclide dose calibrator;
- (b) A refrigerator;
- (c) A single or multiple channel scintillation counter with well-type NaI(Tl) or Ge(Li) detector;
- (d) A radiochemical fume hood and filter system with air sampling equipment;
- (e) An area survey meter;
- (f) At least 2 GM survey meters including one high-range meter;
- (g) A microscope and hemacytometer;

(h) A laminar air flow hood and appropriate supplies to ensure sterile practices for parenteral solutions;

(i) Syringe and vial radiation shields;

(j) A lead-shielded drawing station;

(k) Decontamination supplies;

(l) Supplies to perform quality assurance testing;

(m) Lead transport shields for syringes and vials; and

(n) New Hampshire department of transportation approved USA Type A - 7A approved transport containers and other labels and supplies for shipping radioactive materials.

CHAPTER Ph 500 ETHICAL STANDARDS

PART Ph 501 CODE OF ETHICS

Ph 501.01 Standards of Conduct.

(a) The ethical standards set forth in this part shall bind all licensees, and violation of any such standard shall be a basis for the imposition of disciplinary sanctions.

(b) A licensed pharmacist shall:

(1) Hold the health and safety of patients to be of first consideration and render to each patient the full measure of his/her ability as an essential health practitioner;

(2) Never condone the dispensing, promoting or distributing of drugs or medical devices, or assist therein, which are not of good quality, which do not meet standards required by law or which lack therapeutic value for the patient;

(3) Always strive to perfect and enlarge his/her professional knowledge;

(4) Utilize and make available his/her knowledge as might be required in accordance with his/her best professional judgment;

(5) Observe the law, uphold the dignity and honor of the profession, and accept its ethical principles;

(6) Not engage in any activity that will bring discredit to the profession and shall expose, without fear or favor, illegal or unethical conduct in the profession;

(7) Seek at all times only fair and reasonable remuneration for services rendered;

(8) Never agree to or participate in transactions with practitioners of other health professions or any other person under which fees are divided or which might cause financial or other exploitation in connection with the rendering of their professional services;

(9) Respect the confidential and personal nature of professional records, except in emergency situations where the best interest of the patient requires or the law demands, and shall not disclose such information to anyone without patient authorization;

(10) Not agree to practice under terms or conditions which tend to interfere with or impair the proper exercise of professional judgment and skill, which could cause a deterioration of the quality of his/her service or which require him/her to consent to unethical conduct;

(11) Refrain from advertising professional services in a manner which is misleading to the public or which conveys by implication that the services of fellow pharmacists are unethical or inferior;

(12) Maintain a sanitary and orderly prescription department which is fully equipped and stocked to meet the needs of the community; and

(13) Fulfill all professional obligations conscientiously and with due respect for the physical and well-being of the community, and, uphold at all times the standards of the profession of pharmacy.

CHAPTER Ph 600 LIMITED RETAIL DRUG DISTRIBUTOR

Statutory Authority: RSA 318:51-b

PART Ph 601 LICENSING OF LIMITED RETAIL DRUG DISTRIBUTORS

Ph 601.01 License Required.

(a) No person shall act as a limited retail drug distributor, as defined in RSA 318:1,VII-a, without first obtaining a license to do so from the board according to RSA 318:51-b.

(b) No license shall be issued or renewed for a limited retail drug distributor unless the same shall be operated in a manner prescribed by RSA 318:51-b and according to Ph 600.

(c) Separate licenses shall be required for each site owned and operated by the limited retail drug distributor.

(d) The board shall provide, on an annual basis, a license renewal to all licensed limited retail drug distributors.

(e) The prescribed fee for annual and renewal licenses for limited retail drug distributors shall be:

(1) For clinics under contract with the department of health and human services (DHHS), \$150; and

(2) For methadone maintenance/detoxification treatment centers, \$250.

Ph 601.02 Obtaining and Filing a License Application.

(a) Applications for licensure of limited retail drug distributors may be obtained from and filed at the board office, identified in Ph 103.03.

Ph 601.03 Application Contents.

(a) The applicant for licensure shall supply, on form MM-1, at least the following:

(1) Name of the facility;

(2) Address of the actual location where business is conducted;

- (3) Identification of ownership;
- (4) Hours of operation;
- (5) List of persons with access to the drug supply;
- (6) Signature of the person responsible for the licensed location and date signed;
- (7) Identity of the consultant pharmacist; and
- (8) Identity of the medical director.

(b) The applicant shall also submit a scaled drawing of the facility.

(c) The applicant shall supplement the application specified in (a) and (b) above with any certificates, affidavits, plans, documents or other information sufficient to show full compliance with all of the requirements of part Ph 600.

(d) If the applicant is a corporation, or the limited retail drug distributor will be operated under a corporate name, a certificate from the NH secretary of state attesting to the documents creating the corporate person and any amendment(s) thereof to the certificate of incorporation, or authorizing it to do business in the state of New Hampshire under the corporate name.

(e) If the applicant proposes to hold, store or dispense controlled substances as a methadone maintenance/detoxification facility, the application shall be supplemented with the following information:

- (1) A brief description of the security system; and
- (2) A list of all persons with access to the controlled substances.

(f) The applicant shall supplement the application specified in (a) above with any certificates, affidavits, plans, documents or other information sufficient to show full compliance with all of the requirements for operation of a drug abuse treatment facility.

(g) If the application is for a methadone maintenance/detoxification facility, the applicant shall submit the current registration number issued by the federal drug enforcement administration (DEA).

Ph 601.04 Consultant Pharmacist. All applicants licensed under the provisions of RSA 318:51-b shall have a written contract with a pharmacist, licensed in NH, to serve as a consultant on all matters relating to procurement, storage and dispensing of prescription drugs as defined in RSA 318:1, XVII.

Ph 601.05 Changes in Supporting Information. The applicant shall notify the board, immediately, of any changes of information from that which was submitted on the original application pursuant to Ph 601.03. Failure to report changes shall result in the imposition of a \$25 administrative fee. No license shall be issued until all fees are paid in full.

Ph 601.06 Renewal Applications.

(a) The license period shall be from July 1 thru June 30 of the following year.

(b) Applications for renewal of a license to operate as a limited retail drug distributor shall consist of the application as described in Ph 601.03 and the prescribed fee as indicated in Ph 601.01(e).

Ph 601.07 Temperature. The temperature in any area wherein drugs are stored, manufactured, compounded or dispensed, shall, at all times, be in compliance with the standards established by the United States Pharmacopoeia as defined in Ph 701.02(r).

Ph 601.08 Quarantine. Any drug, which is adulterated as defined in Ph 701.02(a) or misbranded as defined in Ph 701.02(i), shall be removed from the routine stock and held in a specifically designated secure area of the facility pending proper and safe disposition.

Ph 601.09 Space. Drugs shall be housed in a well-lighted and ventilated room or department with clean and sanitary surroundings.

Ph 601.10 Security.

(a) That portion of the facility where drugs are stored, compounded or dispensed, shall be lockable so as to prevent entry into that area by any person or persons without the knowledge of the authorized individuals on duty, or when the facility is not open.

(b) If the facility contains controlled substances, it shall be equipped with a suitable alarm system as referenced in Ph 309.06.

(c) Methadone maintenance/detoxification facilities shall ensure that all access from outside their premises is secure. This shall include, but not be limited to, the installation of adequate lighting to illuminate the outside perimeter of the premises.

(d) All controlled substances shall be stored pursuant to the security provisions outlined in 21 CFR 1301.72(a).

(e) For those facilities which are open to the public 24 or more hours per week, the consultant pharmacist shall visit, at least monthly, all areas of the facility where drugs are stored to ensure that they are properly labeled, have not reached their expiration date and show no signs of deterioration. Any drugs not conforming to these standards shall be removed from stock. For facilities which are open to the public less than 24 hours per week, such visits shall be conducted on a quarterly basis.

(f) The consultant pharmacist shall create a written record of each monthly and/or quarterly inspection, specified in (e), which shall be maintained on site and available to the board upon request.

(g) The pharmacist shall ensure that the areas specified in (e) above are in compliance with federal and state drug laws relative to security, drug distribution and product tampering.

(h) The consultant pharmacist shall develop a distribution system, which shall prevent the illegal diversion of drugs. Where applicable, the inventory of all schedule II controlled substances and other controlled drugs as required by federal law stored in any area of the facility, shall be checked by 2 persons at least every 24 hours and accountability records shall be completed by the nursing or medical staff and maintained on-site for inspection by the consultant pharmacist, except:

(1) In situations at the methadone maintenance/detoxification facilities that result in only one staff member being present, the inventory shall be counted, signed, dated and shall be "cosigned" immediately upon the presence of a second staff member.

(2) At no time shall there lapse more than 72 hours before this inventory verification by a second party.

Ph 601.11 Dispensing Practices.

(a) Drugs shall be dispensed only by or in the presence of and under the supervision of a pharmacist, physician, advanced registered nurse practitioner, physician assistant, or registered nurse, as identified in RSA 318:42, VII (a), in compliance with state and federal pharmacy-related laws and rules.

(b) In the case of methadone maintenance/detoxification facilities and according to the provisions of RSA 318:42, VII(a), the dispensing of narcotics is extended to employees of the clinic, authorized in writing according to the provisions of 21 CFR 1301.74(i) of the federal law.

(c) All drug order deliveries containing prescription drugs shall be delivered only when a licensed practitioner is on the premises in order to secure such drug orders.

(d) In the case of methadone maintenance/detoxification facilities, drug deliveries may be accepted only by the licensed practitioner or other individuals identified according to the requirements of 21 CFR 1301.74(h).

Ph 601.12 Deliveries.

(a) All drug order deliveries containing prescription drugs shall be delivered only when a licensed practitioner is on the premises in order to secure such drug orders.

(b) In the case of methadone maintenance/detoxification facilities, drug deliveries may be accepted only by the licensed practitioner or other individuals identified according to the requirements of 21 CFR 1301.74(h).

Ph 601.13 Access to Drug Supply.

(a) Only the pharmacist, physician, advanced registered nurse practitioner, physician assistant or registered nurse, as identified in RSA 318:42, VII (a), shall have access to the drug supply.

(b) In the case of methadone maintenance/detoxification facilities, access to the drug storage area may also be extended to licensed practical nurses provided such authorization is granted, in writing, according to the provisions of 21 CFR 1301.72(d) of the federal law.

(c) Methadone maintenance/detoxification facilities shall supply the board with a list of all individuals that have been granted access to the drug supply, and, should this list change, the board shall be notified, in writing, within 72 hours of such changes.

Ph 601.14 Dispensing Records.

(a) A readily retrievable record, completed by the nursing or medical staff, shall be made of all administration or dispensing of prescription drugs from the facility.

(b) The record, as specified in (a) above, shall be separate from the patient's medical record and include:

- (1) Name and address of the patient;
- (2) Date of administration or dispensing;
- (3) Name, strength and quantity of drug(s) administered or dispensed;

(4) Identity of the prescriber; and

(5) Signature of the person administering or dispensing.

(c) Methadone maintenance/detoxification facilities shall maintain a dispensing log, completed by the nursing or medical staff, containing the following information:

(1) Name of substance;

(2) Strength of substance;

(3) Dosage form;

(4) Date administered;

(5) Patient identification number;

(6) Amount consumed;

(7) Amount and dosage form taken home; and

(8) Dispenser's signature.

(d) Records of administrations and dispensing as specified in (b) and (c) above shall be maintained for a period of 4 years. Such records shall be open to inspection by the pharmacy board and its agents.

Ph 601.15 Prescription Labels.

(a) Whenever an authorized practitioner dispenses a controlled drug, as defined in RSA 318-B:1-a and b, or a non-controlled prescription drug, as defined in RSA 318:1, XVII, he/she shall affix to the container in which such drug is dispensed, a label showing at least:

(1) Name and address of the facility;

(2) Name of the patient;

(3) Date dispensed;

(4) Name, strength and quantity of drug dispense;

(5) Directions for use;

(6) Name of the prescribing practitioner;

(7) Name or initials of the dispensing practitioner; and

(8) All pertinent auxiliary labels.

Ph 601.16 Labeling Exemption. The labeling requirements, as specified in Ph 601.15, shall be exempted when medication is being administered, for immediate consumption, such as in a methadone maintenance/detoxification facility.

Ph 601.17 Violations. Any person who distributes legend drugs according to RSA 318:51(b) and the provisions of Ph 600, shall be subject to disciplinary action as provided in RSA 318:29.

CHAPTER Ph 700 STANDARDS OF PRACTICE

PART Ph 701 REFERENCES AND DEFINITIONS

Ph 701.01 Applicability. The provisions of this chapter shall apply to, and impose duties upon, all pharmacists, pharmacies, manufacturers, wholesalers and distributors holding licenses issued by the board.

Ph 701.02 Definitions. Except where the context makes another meaning manifest, the following words mean:

- (a) "Adulterated drug" means any drug:
 - (1) That is contaminated, decomposed, deteriorated, sub-potent, super-potent, or otherwise unsafe for administration to man or other animals;
 - (2) Which has been manufactured, composed, prepared, stored, or dispensed in such a manner which may cause it to be contaminated, decomposed, deteriorated, sub-potent, super-potent, or otherwise unsafe for administration to man or other animals; and
 - (3) Which can be defined as an adulterated drug under the provisions of RSA 146:4 or 21 U.S.C. 351 of the Food, Drug, and Cosmetic Act.
- (b) "Device" means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including any component part or accessory, which is required under federal law to bear the label, "Caution: Federal or State law requires dispensing by or on the order of a physician."
- (c) "Distributor" means a person or persons who supplies or facilitates the supply of prescription drugs to someone other than the patient, including, but not limited to, manufacturers, repackers, brokers and wholesale drug distributors.
- (d) "Drug outlet" means all pharmacies, dispensing practitioners, hospitals, drug abuse treatment centers, retail stores, penal institutions, infirmaries, clinics and federal or state facilities that are engaged in delivery or distribution of drugs.
- (e) "Drug room" or "medication room" means that room or area in an institution used to store prescription drugs obtained on individual prescription from an off-premise licensed pharmacy, as well as non-legend drugs.
- (f) "Electronic transmission" means transmission of information in electronic form or the transmission of the exact visual image of a document by way of electronic equipment.
- (g) "Institution" means a health care facility which provides inpatient care and includes:
 - (1) Hospitals;
 - (2) Nursing homes;
 - (3) Extended care facilities;
 - (4) Residential care facilities;
 - (5) Infirmaries;
 - (6) Clinics; and

(7) Correctional facilities.

(h) "Institutional pharmacy" means an area in an institution where drugs are stored, manufactured, compounded, dispensed, or issued to other areas or departments of the institution.

(i) "Misbranded drug" means a drug:

(1) Whose label misrepresents the contents or is misleading;

(2) If dispensed by prescription, a drug whose label does not comply with the provisions of RSA 318 or RSA 318-B; and

(3) Which can be defined as a misbranded drug under the provisions of RSA 146 or federal law.

(j) "NH Pharmacy Law Book" means a publication of the board which contains RSA 318, RSA 318-B and Ph 100 through 700.

(k) "Prescriber" means a practitioner, duly authorized by statute, who issues a drug order or prescription.

(l) "Principal" means an officer, director, or primary stockholder of a business entity or corporation.

(m) "Professional corporation" as used in these rules means a corporation organized under RSA 294-A for the purpose of providing professional services in the field of medicine, dentistry, veterinary, podiatry, or any other profession in which individual practitioners can lawfully possess, dispense, or distribute prescription drugs.

(n) "Signature" means:

(1) The handwritten name of an individual affixed by the hand of that individual to a document;

(2) An electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign a document or record; or

(3) An electronic signature.

(o) "Traditional physician-pharmacist-patient relationship" means a situation whereby the pharmacist knows either the physician, the patient, or both, and/or can readily and easily check on factors concerning the prescription.

(p) "Unit-dose" means a single-unit container that is designed to hold a quantity of drug product intended for administration as a single dose and labeled with the identity, quantity and/or strength, name of the manufacturer, lot number and expiration date of the drug product.

(q) "Unprofessional conduct" means conduct and practices which are hostile to the protection of public health, safety and welfare and includes:

(1) Knowingly engaging in any activity which violates state and federal statutes, regulations and rules governing the practice of pharmacy;

(2) Knowingly dispensing an outdated product;

- (3) Knowingly charging for more dosage units than are actually dispensed;
- (4) Knowingly altering prescriptions or other records which the law requires the pharmacy or pharmacist to maintain;
- (5) Knowingly dispensing medication without proper authorization or prescription;
- (6) Defrauding any persons or government agency receiving pharmacy services; or
- (7) Placing a signature on any affidavit pertaining to any phase of the practice of pharmacy which the pharmacist knows to contain false information.

(r) "USP" means the United States Pharmacopeia, published by and issued under the authority of the Pharmacopeial Convention, which provides recognized standards and specifications for all drug entities in the U.S.

(s) "Wholesale drug distribution" means distribution of prescription drugs other than to the patient, including, but not limited to distribution by manufacturers, repackers, own label distributors, jobbers, and wholesale drug distributors.

Ph 701.03 References. Persons subject to these rules shall comply with the following regulations and statutes as cited:

- (a) RSA 146, Purity and Branding of Foods and Drugs;
- (b) RSA 318, Pharmacists and Pharmacies;
- (c) RSA 318-B, the New Hampshire Controlled Drug Act;
- (d) 21 USC Sections 321 through 374, the Federal Food, Drug, and Cosmetic Act;
- (e) 21 CFR 1300 to end; and
- (f) The United States Pharmacopeia.

PART Ph 702 PHARMACY FACILITIES AND EQUIPMENT

Ph 702.01 Area, Space and Fixtures.

(a) Pharmaceuticals, library and equipment shall be housed in a well lighted and ventilated room or department with clean and sanitary surroundings devoted primarily to the compounding of prescriptions. This portion of a pharmacy shall have an area of not less than 200 square feet. No area shall be included in the calculation of the minimum area required by this section unless that area is used exclusively for the storage, manufacture, compounding, and dispensing of drugs.

- (b) The space primarily devoted to the compounding of prescriptions shall be equipped with:
 - (1) Necessary counters and storage cabinets;
 - (2) A sink with hot and cold running water; and
 - (3) Refrigeration storage equipment used exclusively for drugs.

(c) Upon written request by an institution the board shall waive minimum area requirements for institutional pharmacies upon a showing that the extent of pharmaceutical services provided does not require the full 200 square feet.

Ph 702.02 Temperature. The temperature in any area wherein drugs are stored, manufactured, compounded or dispensed, shall, at all times be in compliance with the standards established by the latest edition of the United States Pharmacopeia.

Ph 702.03 Quarantine. Any drug which is adulterated or misbranded shall be removed from routine stock and held in a specifically designated area of the pharmacy pending proper and safe disposition.

Ph 702.04 Security.

(a) That portion of a pharmacy wherein drugs are stored, manufactured, compounded or dispensed, shall, when the pharmacy is open, be so designed and constructed as to prevent entry into that area by any person or persons without the knowledge of the pharmacist then on duty, or when the pharmacy is not open to the public, by the activation of an alarm.

(b) The pharmacy shall be equipped with an alarm system which, when activated, shall emit a signal which is:

- (1) Audible to the average person situated outside the building in which the pharmacy is located, at least 100 feet from any point of that building, or the public highway closest to that building, whichever is greater; or
- (2) Observable by a law enforcement or security officer situated in a station of the law enforcement organization having jurisdiction over the area in which the pharmacy is located or in an office of a security organization serving the area in which the pharmacy is located.

(c) In order to be adequately designed and constructed, within the meaning of this section, a pharmacy shall be equipped with a door or doors capable of being locked.

Ph 702.05 Limitations on Access.

(a) Except as provided in Ph 704.01(b), no pharmacy shall be open unless a pharmacist is on duty in the pharmacy. At all times during which a pharmacist is not on duty in the pharmacy, all entry to the pharmacy shall be barred by locked doors.

(b) The keys to the locked doors of a pharmacy shall be possessed only by:

- (1) The pharmacist-in-charge;
- (2) Pharmacists in the employ of the pharmacy;
- (3) A non-pharmacist owner or owners of the pharmacy;
- (4) Qualified security personnel as shall be designated by the pharmacist-in-charge and a list of such personnel shall be filed with the board by the pharmacist-in-charge; or
- (5) If an institutional pharmacy, administrators of the institution and those nurses designated to enter the pharmacy to obtain medications in emergency situations.

(c) A non-pharmacist owner or owners may be on the premises of a pharmacy which he or she owns in the absence of a pharmacist employed by that pharmacy, provided that the pharmacy is not open and no drugs are compounded, dispensed or sold.

(d) The pharmacy permit shall be issued to the pharmacy in the name of the pharmacist-in-charge, who shall have sole control and responsibility for the operation of the pharmacy in accordance with all laws and rules pertaining to the practice of pharmacy in this state and always in the best interest of public health and safety.

Ph 702.06 Minimum Drug Standards. Registrants shall comply with the minimum drug standards set forth in the latest edition of the United States Pharmacopeia (USP).

Ph 702.07 Minimum Standard of Technical Equipment and Stock. Every pharmacy shall have contained therein, at all times, the following:

(a) Prescription labels showing the name, address, telephone number and DEA number of the pharmacy;

(b) An assortment of auxiliary labels or the software to produce them;

(c) A current reference library, or the ability to access references on line, as determined by the pharmacist-in-charge, to meet the needs of the practice, and specialties, of that pharmacy and the patients it serves; and

(d) A current copy, with supplements, or the ability to access on line within the licensed area the New Hampshire Pharmacy Law Book.

PART Ph 703 RECORDS AND REPORTS

Ph 703.01 Recordkeeping Requirements. The requirements of Ph 703 shall be in addition to all record keeping and reporting requirements contained in all federal and state statutes and regulations.

Ph 703.02 Bulk Compounding.

(a) Each pharmacy shall maintain a series of records, separate from all other records, and used exclusively for the recording of data regarding compounding for direct patient dispensing of drugs.

(b) The pharmacist who compounds or supervises the compounding of prescription drugs in bulk, shall maintain a written record that contains at least the following information:

(1) The formula of the compound;

(2) The identity of the manufacturer or source of the bulk chemicals, the lot number and the expiration date of each ingredient contained in the formula;

(3) The assigned in-house, quality control lot number, date of compounding and an expiration date which shall not exceed one year; and

(4) The name or initials of the compounding pharmacist.

Ph 703.03 Prepackaging of Drugs.

(a) Drugs shall be prepackaged in quantities suitable for internal distribution only by a pharmacist or by supportive personnel under the direct supervision of a pharmacist.

(b) The label of a prepackaged unit shall indicate the:

- (1) Brand name and strength of the drug, or if no brand name, the generic name, strength, and name of the manufacturer or distributor;
- (2) Assigned in-house, quality control lot number;
- (3) Expiration date; and
- (4) Quantity of the drug, if the quantity is greater than one.

(c) The pharmacist who prepackages or supervises prepackaging shall maintain a written record that contains at least the following information:

- (1) Name of the drug, strength, and dosage form;
- (2) Assigned in-house, quality control lot number;
- (3) Manufacturer or distributor;
- (4) Manufacturer's lot number;
- (5) Expiration date;
- (6) Quantity per prepackaged unit;
- (7) Number of prepackaged units;
- (8) Date packaged;
- (9) Name or initials of the packer; and
- (10) Signature of the responsible pharmacist.

(d) Stock packages, repackaged units, and control records shall be quarantined together until checked/released by the pharmacist.

Ph 703.04 Controlled Drug Losses.

(a) The pharmacist-in-charge shall report to the board the loss or suspected loss of any controlled drug from his or her pharmacy. The pharmacist-in-charge shall notify the board by phone within 72 hours of the loss followed by a written report signed by the pharmacist-in-charge, on DEA Form 106, as set forth in 21 CFR 1301.76(b) and mailed to the board not later than 15 days after the pharmacist-in-charge discovered that controlled drugs were missing from his or her pharmacy.

(b) The written report referenced in (a) shall contain at least the following:

- (1) Date of discovery;
- (2) The identity of the person making the discovery;
- (3) The name and location of the pharmacy from which the drug is missing; and

(4) The identity and quantity of the missing drug(s).

Ph 703.05 Automated Data Processing Systems. As an alternative to the procedures provided in RSA 318, RSA 318-B and these rules, an automated data processing system may be used for the storage of original prescriptions and the retrieval of refill information for all prescription orders including, but not limited to, controlled substances in schedules II, III, IV, and V, as defined in 21 CFR 1308.11-1308.15 subject to the following conditions:

(a) The system shall provide security against improper manipulation or alteration of stored records. Individual access codes shall be unique to each licensed location and shall not be available to any other location.

(b) A pharmacy shall make arrangements with the supplier of data processing services or materials to assure that the pharmacy continues to have access to the complete prescription and dispensing records if the relationship with such supplier terminates for any reason. A pharmacy shall assure continuity in the maintenance of records for the protection of public health.

(c) If an automated data processing system is used for the storage and retrieval of refill information for prescription orders as authorized by Ph 703.05, the pharmacy may use a traditional handwritten system only to satisfy the requirements of Ph 703.05(n).

(d) Each pharmacist in charge of a licensed pharmacy which utilizes an automated data processing system shall comply with all provisions of this section.

(e) Any such proposed computerized system shall provide on-line retrieval, via electronic display or hard-copy printout, of all prescription records processed at that licensed location.

(f) The information required by (e) above shall include:

(1) The original prescription number;

(2) The date of issuance of the original prescription order by the practitioner;

(3) The full name and address of the patient;

(4) The name, address, and DEA registration number of the practitioner, when applicable; and

(5) The name, strength, dosage form, quantity prescribed, and quantity dispensed if different from the quantity prescribed, and the total number of refills authorized by the prescribing practitioner, if any.

(g) Any such proposed computerized system shall also provide on-line retrieval, via electronic display or hard-copy printout, of the current refill history of all prescription orders including controlled substances in schedules III, IV, and V.

(h) This refill history shall include:

(1) The name of the drug;

(2) The date of refill;

(3) The quantity dispensed;

(4) The identification code, or name or initials of the dispensing pharmacist for each refill; and

(5) The total number of refills dispensed to date for that prescription order.

(i) When filing refill information for original prescription orders for schedules III, IV, and V controlled substances, a pharmacy shall use only a computerized system or a non-computerized system.

(j) Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original prescription order, including refill orders for a schedule III, IV, or V controlled substances is correct shall be provided by:

(1) A hard-copy printout of each day's controlled substance prescription order refill data which shall be verified, dated, and signed by each pharmacist who refilled such prescription orders; or

(2) In lieu of such a printout, the pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him and is correct as shown.

(k) The hard-copy printout and the log book referenced in (j) above shall be kept at the pharmacy, in a separate file, for a period of 4 years from the dispensing date.

(l) The computerized system shall have the capability of producing a printout of all refill data and shall include:

(1) A refill-by-refill audit trail for any specified strength and dosage form of any controlled substance;

(2) Name of the prescribing practitioner;

(3) Name and address of the patient;

(4) Quantity dispensed on each refill;

(5) Date of the dispensing for each refill;

(6) Name or identification code of the dispensing pharmacist; and

(7) The number of the original prescription order.

(m) In any computerized system employed by a user pharmacy, the central recordkeeping location shall be capable of sending the printout to the pharmacy within 48 hours.

(n) In the event that a pharmacy which employs such a computerized system experiences system down-time, the pharmacy shall have an auxiliary procedure which shall be used for documentation of all refills including authorized refills of schedules III, IV, and V controlled substance prescription orders. This auxiliary procedure shall ensure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data is retained for on-line data entry as soon as the computer system is available for use again.

(o) Each pharmacy using an automated data processing system shall maintain on file a hard copy of all prescriptions preserving all information contained on the original written or oral prescription. Any

computer generated material shall be affixed to the rear of the prescription, leaving the face of the prescription intact.

(p) Computer-produced prescription container labels shall comply with RSA 318:47 (a), RSA 318:47-b and RSA 318-B:13, II.

(q) Institutional pharmacies located in hospitals, clinics or nursing homes and providing pharmacy services for in-patients only, as well as providers of pharmaceutical services to institutions from an off-premise location and utilizing a unit dose drug distribution system, shall be exempt from the provisions of this rule provided that:

- (1) The pharmacist-in-charge submits a written request for exemption to the board of pharmacy;
- (2) Written policies and procedures detailing the drug distribution system are available at the institution for inspection; and
- (3) The system provides for a simple, accurate, and timely audit trail for all controlled substances.

(r) In the event that a pharmacy using an electronic data processing system for storage and retrieval of prescription information goes out of business, sells out to another pharmacy that does not wish to use such a system, or discontinues use of the computer system, the seller pharmacy shall:

- (1) Notify the board of pharmacy in writing at least 30 days prior to discontinuance of said system;
- (2) Provide an up-to-date hard-copy printout of all non-controlled drug prescriptions stored in the automated system for one year and a printout of all controlled drug prescriptions for the current 2 year period as part of the final records of that pharmacy prior to a change over to a manual system; and
- (3) Make provision for these records to be available to any nearby pharmacy in the event that the pharmacy closes, as provided in Ph 708.02.

Ph 703.06 Federal DEA #222 Order Forms. All used DEA #222 order forms or any successor forms shall be maintained on the premises to which the forms and the corresponding DEA permit number were issued. In the case of on-line ordering of CII drugs, all records of such must be maintained on said premises and be readily retrievable. Such records shall meet the requirements of federal laws and regulations and shall be maintained for a period of not less than 2 years.

Ph 703.07 Inspection Report. The current compliance inspection report of the licensed location, conducted by the board, shall be posted conspicuously in the prescription department.

PART Ph 704 DISPENSING OF DRUGS AND DEVICES

Ph 704.01 Presence of Pharmacists.

(a) Prescription drugs and devices shall be dispensed only in the presence of and under the immediate supervision of a pharmacist except as provided in (b).

(b) Whenever the pharmacy is staffed by a single pharmacist, the pharmacist may take a lunch/rest break for a period of up to 30 minutes without closing the pharmacy and removing pharmacy technicians

and pharmacy interns from the pharmacy if the pharmacist reasonably believes that the security of the prescription drugs will be maintained in his or her absence and in accordance with the following:

- (1) Lunch breaks shall be scheduled as close as possible to the same time each day in order for the patients to become familiar with the approximate times of lunch breaks;
- (2) Lunch breaks shall be part of the total hours worked each week;
- (3) The pharmacist shall remain on the store premises during the lunch break and be available for emergencies. Emergencies shall be defined by the patient.
- (4) If 2 or more pharmacists are on duty, the pharmacists shall stagger their lunch breaks so that the pharmacy is not left without a pharmacist on duty;
- (5) Whenever the pharmacist temporarily leaves the prescription department for a lunch break, a sign indicating that there is no pharmacist on duty shall be conspicuously displayed in full view of patients approaching the prescription department service area. The signage shall also indicate the time when the pharmacist is to return;
- (6) Only pharmacy technicians or pharmacy interns authorized by the pharmacist on duty may remain in the pharmacy while the pharmacist is on lunch break;
- (7) During such times that the pharmacist is temporarily absent from the pharmacy, only pharmacy technicians or pharmacy interns duly authorized by the pharmacist on duty may continue to perform non-discretionary duties as delineated by the pharmacist. However, all duties performed by the technicians or interns shall be reviewed by the pharmacist upon his or her return from break;
- (8) When a pharmacist is not in the pharmacy, there shall be no dispensing or sale of new prescriptions that the pharmacist has checked and are waiting to be picked up nor shall counseling be provided by the pharmacy technician or pharmacy intern;
- (9) New, written prescriptions, presented in person by the patient or his agent, may be accepted by the pharmacy technician or pharmacy intern and the processing of that prescription, up to the final check, may occur during the absence of the pharmacist. However, no new prescriptions may be dispensed or sold until the final check is completed by the pharmacist on his or her return;
- (10) New prescriptions conveyed by telephone shall not be accepted and the caller shall be instructed to call back or a telephone number obtained for the pharmacist to call upon his or her return;
- (11) During the pharmacist's absence, prescription refills which have been previously prepared and checked by a pharmacist may be picked up by the patient or his agent. If the patient has no questions, the sale may proceed as normal with the patient signing a statement indicating the refusal of counseling by the pharmacist. If the patient desires counseling, he or she shall be asked to wait for the pharmacist to return from break or, alternatively, asked to leave a telephone number for the pharmacist to call later that day;
- (12) Telephone refill orders as well as refill requests presented, in person, by the patient or his agent, may be accepted by the pharmacy technician or intern and such refill orders may be processed by the technician or intern up to the final check. However, no such refill orders shall be dispensed or sold until the final check is completed by the pharmacist on his or her return from break;

(13) A pharmacist who takes a lunch break in compliance with this protocol shall not be subject to New Hampshire state board of pharmacy disciplinary action or board citation for acts that he or she did not authorize and that he or she, by the exercise of reasonable care, could not have prevented during his or her absence; and

(14) If in the professional judgment of the pharmacist, for reasons of security or otherwise, the pharmacist determines that the pharmacy should close during his or her absence, then the pharmacist shall close the pharmacy. All pharmacy technicians and pharmacy interns shall be removed from the pharmacy during his or her absence. A sign informing the public of the pharmacist's return shall be conspicuously posted.

Ph 704.02 Pre-signed Prescription Blanks. No person shall possess, and no pharmacy shall have within it, any document signed by a prescriber which, if completed, would be usable as a prescription.

Ph 704.03 Transmission of Prescription Drug Order by Prescriber.

(a) A prescription drug order may be transmitted to a pharmacy by an authorized prescriber or his designated agent in writing, orally or electronically.

(b) An electronically transmitted prescription drug or device order shall:

(1) Be sent to the pharmacy of the patient's choice;

(2) For a non-controlled substance prescription drug or device order, include:

a. The name of the patient;

b. The name, strength, and quantity of the drug prescribed;

c. Any directions specified by the prescribing practitioner;

d. The name and address of the prescribing practitioner which shall be printed or typewritten;

e. The prescribing practitioner's phone number for verbal confirmation; and

f. The date the prescription was ordered.

(3) For a schedule II through V controlled substance prescription drug order, as defined in RSA 318-B:1-b and transmitted by facsimile, or as an electronic prescription, include:

a. The name and address of the patient;

b. The name, strength, and quantity of the drug prescribed;

c. Any directions specified by the prescribing practitioner;

d. The full name of the prescribing practitioner which shall be printed, rubber stamped, or typewritten above or below his or her handwritten signature or an electronic signature seen valid by the Drug Enforcement Agency (DEA) for electronic prescriptions;

e. The address of the prescribing practitioner;

f. The federal drug enforcement administration (DEA) number assigned to the prescribing practitioner; and

g. The date the prescription was ordered.

(c) The pharmacist shall exercise professional judgment regarding the accuracy and authenticity of the electronically transmitted prescription drug order which shall be consistent with existing federal or state laws and rules.

(d) For controlled substances in schedules II, III, IV or V, as defined in RSA 318-B:1-b, a pharmacy may receive an electronically transmitted drug order from the prescriber for filling provided that it is transmitted in accordance with federal law.

(e) There shall be 3 exceptions to the requirements stated in (d) above:

(1) A prescription prepared in accordance with RSA 318-B:9, III and IV, and issued for a schedule II substance, as defined in RSA 318-B:1-b, to be compounded for the direct administration to a patient in a private residence, long-term care facility, or hospice setting, by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be electronically transmitted, by the practitioner or the practitioner's designated agent to the dispensing pharmacy. The printed copy of the transmission shall serve as the original written prescription and shall be maintained in accordance with the provisions of RSA 318-B:9, I;

(2) A prescription prepared in accordance with RSA 318-B:9, III and IV, and issued for a schedule II substance, as defined in RSA 318-B:1-b, for a resident of a long-term care facility may be electronically transmitted by the practitioner or the practitioner's designated agent to the dispensing pharmacy. The printed copy of the transmission shall serve as the original written prescription and shall be maintained in accordance with the provisions of RSA 318-B:9, I; and

(3) A prescription prepared in accordance with RSA 318-B:9, III and IV, and issued for a schedule II substance, as defined in RSA 318-B:1-b, for a patient enrolled in a hospice care program, may be electronically transmitted by the practitioner or the practitioner's designated agent to the dispensing pharmacy. The practitioner or the practitioner's designated agent shall note on the prescription that the patient is a hospice patient. The printed copy of the transmission shall serve as the original written prescription and shall be maintained in accordance with the provisions of RSA 318-B:9, I.

(g) The device used for the receipt of electronically transmitted prescription drug orders shall be located in the prescription department of the pharmacy in order to protect patient confidentiality and to assure security.

Ph 704.04 Transfer of Prescriptions. Original prescription drug order information for drugs may be transferred between pharmacies for the purpose of refill dispensing subject to the following:

(a) The transfer shall be communicated directly between 2 licensed pharmacists;

(b) The transferring pharmacist shall:

(1) Write the word "VOID" on the face of the prescription for controlled substances;

(2) Note in the patient medication record that a copy has been issued, the date of transfer, and the name of the pharmacist transferring the prescription; and

(3) Record in the patient medication record the name and address of the pharmacy to which the prescription was transferred and the name of the pharmacist receiving the prescription information.

(c) When a prescription is transferred, no further refills shall be issued by the transferring pharmacy.

(d) The pharmacist receiving the transferred prescription information shall:

(1) Write the word "transfer" on the face of the transferred prescription; and

(2) Provide all information required to be on the prescription including the:

a. Patient's name and address;

b. Doctor's name and address;

c. Date of issuance of the original prescription and date of transfer;

d. Number of valid refills remaining and date of last refill;

e. Pharmacy name, address, and original prescription number from which the prescription information was transferred;

f. Full name of the transferor pharmacist; and

g. DEA registration number of the transferor pharmacy for controlled substances.

(e) The pharmacist shall maintain both the original and transferred prescription as if they were original prescriptions.

(f) A transferred prescription may be refilled, without limitation, up to the number of remaining refills, as originally authorized, or up to one year from the date of original issue, whichever shall occur first.

(g) The transfer of original prescription drug order information for controlled substances listed in Schedule III, IV or V shall conform to the requirements of 21 CFR 1306.26 and shall be permissible between pharmacies on a one-time basis and shall not be further transferred.

(h) For noncontrolled drugs, 2 or more pharmacies may establish and use a common electronic file to maintain required dispensing information. Pharmacies using such a common electronic file shall not be required to physically transfer prescriptions or information for dispensing purposes between or among pharmacies participating in the same common prescription file, except that any such common file shall contain complete and adequate records of such prescription and the date and location of each refill dispensed and provisions shall be made to assure that the number of authorized refills shall not be exceeded.

(i) Institutional pharmacies may receive and dispense electronically transmitted prescription drug orders for inpatients.

(j) A pharmacist may dispense original, inpatient prescription drug orders received by electronic transmission from a health care facility.

Ph 704.05 Schedule V Controlled Substances.

(a) A Schedule V drug which does not require a prescription as set forth in 21CFR 1306.15 and 21 CFR 1306.32 shall only be sold at retail without a prescription by a licensed pharmacist and not by a non-pharmacist employee even if under the direct supervision of a pharmacist. However, after the pharmacist has fulfilled his or her professional and legal responsibilities as set forth in this section, the cash/credit transaction or delivery may be completed by a non-pharmacist.

(b) A pharmacist shall exercise professional discretion in the sale of a Schedule V drug, as referenced in (a), to insure that the product is being sold for medical purposes only.

(c) A Schedule V drug, as referenced in (a), shall only be sold at retail without a prescription to a person at least 18 years of age. The pharmacist shall require every retail purchaser of a non-legend Schedule V product to furnish a suitable identification, including proof of age when appropriate, in order to purchase a non-legend Schedule V product. The name and address obtained from such identification shall be entered in the record of disposition to consumer.

(d) All cough syrups containing codeine shall not be dispensed without a prescription.

Ph 704.06 Drug Product Selection.

(a) Unless instructed otherwise by the person receiving the drug pursuant to the prescription, a pharmacist filling a prescription for a drug product prescribed by its trade or brand name may select a therapeutically equivalent drug product with the same established name, active ingredient, strength, quantity and dosage form as the drug product identified in the prescription.

(b) Therapeutically equivalent drugs shall include only those drug products listed in "Approved Prescription Drug Products with Therapeutic Equivalence Evaluations" Published by the United States Department of Health and Human Services, according to RSA 146-B:2, I, or any written notification or confirmation from the federal Food and Drug Administration (FDA) that a drug product is a therapeutically equivalent drug product.

(c) The pharmacist shall not select an equivalent drug product:

- (1) If the prescriber handwrites "medically necessary" on the written prescription;
- (2) If when ordering a prescription orally, the prescriber specifies that the prescribed drug is medically necessary; or
- (3) If the prescription is electronically transmitted, the prescriber includes a statement on the face of the prescription indicating medically necessary.

(d) The pharmacist shall not select an equivalent drug product unless its price to the purchaser is less than the price of the prescribed drug product.

(e) The pharmacist or the pharmacist's agent, assistant or employee shall inform the person receiving the drug pursuant to the prescription of the selection of a lower-cost equivalent drug product and of the person's right to refuse the product selected.

(f) Unless the prescriber instructs otherwise, the label for every drug product dispensed shall include the product's trade or brand name, if any, or its established generic name and the name of the manufacturer, packer or distributor, using abbreviations such as the National Drug Code (NDC) number if necessary. In the interest of public health and safety, the pharmacist may, when dispensing a generic drug, include the brand name on the prescription label following the generic name. The brand name,

however, shall be preceded or followed with the word "sub", indicating substituted for, or "I.C.", indicating interchanged for or "generic for".

(g) The pharmacy file copy of every prescription shall include the trade or brand name, the name of the manufacturer, and the packer or distributor of the drug product dispensed.

Ph 704.07 Return of Drugs and Devices.

(a) Except as provided in Ph 704.07(b), no drug, prescription, device, sickroom supply or item of personal hygiene which is returned to the pharmacy shall be re-sold or re-dispensed after such item has been taken from the premises where sold, distributed or dispensed.

(b) Exceptions to Ph 704.07 (a) shall include:

- (1) Orthopedic appliances;
- (2) Crutches;
- (3) Canes;
- (4) Wheelchairs;
- (5) Hospital beds;
- (6) Bed rails;
- (7) Trapezes;
- (8) Other durable equipment that can be properly sanitized; and
- (9) Medications dispensed in unit-dose packaging to institutionalized patients.

Ph 704.08 Prescription Pick-up and Delivery.

(a) No person licensed under the provisions of RSA 318, shall enter into or participate in any arrangement or agreement whereby prescriptions may be left at, picked up from, accepted by, or delivered to any store, shop or location not licensed as a pharmacy.

(b) This section shall not prohibit a licensee from picking up prescriptions or delivering prescribed medications at the residence of the patient, or directly to the patient at his/her workplace, or at the institution in which the patient is confined, by means of an employee or by use of a common carrier.

Ph 704.09 Dispensing Adulterated or Misbranded Drugs. A pharmacist shall not dispense or sell to the public any drug which is adulterated or misbranded. After notice and opportunity for a hearing, a pharmacist who is found by the board to have knowingly dispensed or otherwise sold for consumption an adulterated or misbranded drug, shall be subject to disciplinary action according to RSA 318:29.

Ph 704.10 Out-of-State Prescriptions. Prescriptions written by physicians in a state other than New Hampshire may be dispensed to a patient only when the traditional physician-pharmacist-patient relationship exists.

Ph 704.11 Pharmacist-in-Charge/Corporate Entity Requirements/Duties.

(a) The pharmacist-in-charge or the pharmacist on duty shall control all aspects of the practice of pharmacy.

(b) The pharmacist-in-charge shall be responsible for the control of all drugs issued or dispensed in the pharmacy where he/she practices as well as:

- (1) Establishing written policies and procedures for the procurement, storage, compounding and dispensing of drugs
- (2) Ensuring that all staff pharmacists are familiar with and in compliance with the established policies and procedures;
- (3) Supervising personnel in the prescription department;
- (4) Establishing and supervising the recordkeeping system for the purchase, sale, possession, storage, and repackaging of drugs;
- (5) Maintaining the security of the prescription department and its contents;
- (6) Determining who will have keys and access to the pharmacy;
- (7) Ensuring the medication dispensed is in conformance with the prescription received;
- (8) Prohibiting the presence of misbranded drugs in the pharmacy; and
- (9) Ensuring compliance with the provisions of RSA 318 and RSA 318-B and any other state or federal pharmacy-related laws or rules.

(c) A pharmacist may serve as a pharmacist-in-charge for a maximum of 2 pharmacies, providing that one of these pharmacies shall be in an institution requiring the services of a pharmacist only on a part-time basis.

Ph 704.12 Termination of Pharmacist-in-Charge Notice. Whenever a pharmacist-in-charge shall cease performing that function, that pharmacist-in-charge shall notify the board in writing of the date upon which the cessation of that function is effective. That pharmacist-in-charge shall remain responsible for compliance, in the pharmacy in which he or she was the pharmacist-in-charge, with all pharmacy-related statutes and rules until the effective date of termination.

Ph 704.13 Termination of Pharmacist-in-Charge - Inventory. Whenever a pharmacist-in-charge shall cease performing that function in a pharmacy, the new pharmacist-in-charge shall, within 3 days, cause to be completed a written inventory of all controlled substances located in that pharmacy. The record of that inventory shall be retained in the pharmacy for a minimum of 4 years.

Ph 704.14 Prescription Refill Limitations.

(a) Prescriptions bearing "PRN", "Ad lib" or other similar prescription refill designation permitting the pharmacist to refill the prescription as needed by the patient, shall be refilled only in keeping with the number of doses ordered and according to the directions for use, and in no instance shall such prescription be refilled beyond one year from the date of issue. If additional medication is needed thereafter, the original prescription shall be voided and a new prescription obtained.

(b) No prescription containing either specific or "PRN" refill authorization shall be refilled after the prescribing practitioner ceases to practice:

- (1) Due to license suspension or revocation;
- (2) If he/she no longer maintains a valid NH license;
- (3) If prescribing limitations are placed on a practitioner's license by any state or federal licensing agency which impact on certain previously refillable prescriptions; or
- (4) Due to death.

(c) Notwithstanding (a) and (b) above, the pharmacist may dispense an additional refill supply according to the provisions of Ph 704.15.

Ph 704.15 Prescription Refill - Interim Supply. A pharmacist shall exercise professional judgment in refilling a prescription drug order, including controlled substances listed in Schedules III, IV and V, without the authorization of the prescribing practitioner, provided that:

(a) A failure to refill the prescription might result in an interruption of a therapeutic regimen or create patient suffering;

(b) Either:

(1) A natural or man-made disaster has occurred which prohibits the pharmacist from being able to contact the practitioner; or

(2) The pharmacist is unable to contact the practitioner;

(c) The quantity of prescription drug dispensed does not exceed a 72-hour supply as specified on the original prescription;

(d) The pharmacist informs the patient or the patient's agent at the time of dispensing that the interim supply shall be final and that authorization by the practitioner shall be required for future refills; and

(e) The pharmacist shall inform the prescribing practitioner of the limited emergency supply, provided to the patient, at the earliest reasonable time.

Ph 704.16 Acts Prohibited. Splitting fees, making rebates, or sharing money received for pharmaceutical services, or the donation of and/or the use of equipment with other health practitioners or with health institutions providing patient care shall be deemed by the board to be contrary to the best interests of the patient, and shall therefore be prohibited.

PART Ph 705 STORAGE OF DRUGS

Ph 705.01 Temperature. All drugs shall, at all times, be stored at a temperature which complies with the standards established by the latest edition of the United States Pharmacopeia.

Ph 705.02 Prescription Drugs. All prescription drugs shall be stored in an area which is under the immediate control of a pharmacist and not accessible to unauthorized persons.

Ph 705.03 Emergency Drug Kits for Long Term Care Facilities/Specialized Care Facilities.

(a) "Emergency drug kit" means a select supply of drugs and/or biologicals located at the licensed institution for the immediate administration to patients/residents upon the order of a practitioner as set forth in rules adopted under RSA 151.

(b) Emergency drug kits shall be allowed as set forth in rules adopted under RSA 151.

(c) Non-controlled legend drugs may be stored in the emergency drug kit as deemed necessary and jointly approved by the pharmacist, medical director and the director of nursing services.

(d) The placement of controlled substances in emergency drug kits in non-federally registered long term care facilities/specialized care facilities shall be deemed to be in compliance with the Comprehensive Drug Abuse Prevention and Control Act of 1970 provided that:

(1) Controlled substances shall be stored in the emergency drug kit as deemed necessary and jointly approved by the pharmacist, medical director and the director of nursing services;

(2) The source from which controlled substances for emergency drug kits are obtained shall be a DEA registered hospital, clinic, pharmacy or practitioner;

(3) Controlled substances in emergency drug kits shall be limited to a maximum of 8 separate drug entities with not more than 8 single-use containers of each drug entity;

(4) The emergency drug kit containing controlled substances shall be closed with a tamper proof seal and kept in a locked medication room, cart or closet;

(5) Only the director of nursing services, registered nurse on duty, licensed practical nurse on duty, pharmacist or practitioner shall have access to controlled substances stored in an emergency drug kit;

(6) Controlled substances in emergency drug kits shall be administered to patients only by authorized personnel and only as expressly authorized by an individual practitioner and in compliance with the provisions of 21 CFR 1306.11 and 1306.21;

(7) A usage record shall be contained in the emergency drug kit for each separate drug included which shall be completed by the nursing staff when using any controlled substance or substances from the kit;

(8) The pharmacist shall receive and file for 4 years a copy of all completed usage records;

(9) When the emergency drug kit is opened:

a. The pharmacist shall be notified by the facility within 24 hours; and

b. Shift counts shall be done by the nursing staff on all controlled substances until resealed by the consultant pharmacist.

(10) Shift counts of the controlled substances contained in the emergency kit shall not be required when the kit is sealed;

(11) The pharmacist shall check the controlled substances in the emergency drug kit at least monthly and so document inside the kit; and

(12) The placement of controlled substances in emergency drug kits shall be only upon the written authorization of the board of pharmacy.

(e) In addition to an emergency box or stat-drug box, a long term care facility, in which only those persons licensed to administer are administering drugs, may maintain a stock of intravenous fluids, irrigation fluids, heparin flush kits, medicinal gases, sterile water and saline, and prescription devices. Such stock shall be limited to a listing to be determined by the provider pharmacist in consultation with the medical and nursing staff of the institution.

PART Ph 706 PHARMACEUTICAL CARE STANDARDS

Ph 706.01 Patient Records.

(a) A patient record system shall be maintained by all pharmacies for patients for whom prescriptions are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription is presented for dispensing.

(b) The pharmacist or supportive personnel shall make a reasonable effort to obtain, record, and maintain the following information:

- (1) The full name of the patient for whom the drug is intended;
- (2) The address and telephone number of the patient;
- (3) The patient's age or date of birth;
- (4) The patient's gender;
- (5) A list of all prescription drug orders obtained by the patient at the pharmacy maintaining the patient record during the 12 months immediately preceding the most recent entry showing:
 - a. The name of the drug or device;
 - b. The prescription number;
 - c. The name and strength of the drug;
 - d. The quantity and date received; and
 - e. The name of the prescriber.
- (6) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(c) The pharmacist shall make a reasonable effort to obtain from the patient or the patient's agent, and record, any known:

- (1) Allergies;
- (2) Drug reactions;
- (3) Idiosyncrasies;
- (4) Chronic conditions or disease states of the patient; and
- (5) Usage of other drugs, including over-the-counter drugs, or medical devices currently being used by the patient.

(d) A patient record shall be maintained for a period of not less than 12 months from the date of the last entry in the profile record. This record shall be a hard copy or a computerized form.

Ph 706.02 Prospective Drug Review.

(a) A pharmacist shall review the patient record and each prescription presented for dispensing for purposes of identifying:

- (1) Over-utilization or under-utilization;
- (2) Therapeutic duplication;
- (3) Drug-disease contraindication;
- (4) Drug-drug interactions;
- (5) Incorrect drug dosage or duration of drug treatment;
- (6) Drug-allergy interactions; and
- (7) Clinical abuse or misuse.

(b) Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the problem which might include consultation with the prescriber.

Ph 706.03 Patient Counseling.

(a) Upon receipt or delivery of a new prescription and following a review of the patient's record, a pharmacist or his/her designee, shall orally offer to discuss matters which will enhance or optimize drug therapy with each patient or caregiver of such patient.

(b) Patient counseling shall:

- (1) Be by the pharmacist and in person, whenever practicable, or by telephone; and
- (2) Include appropriate elements of patient counseling, such as the following:
 - a. The name and description of the drug;
 - b. The dosage form, dose, route of administration, and duration of drug therapy;
 - c. Intended use of the drug and expected action;
 - d. Special directions and precautions for preparation, administration, and use by the patient;
 - e. Common side or adverse effects or interactions and therapeutic contraindications that might be encountered, including their avoidance, and the action required if they occur;
 - f. Techniques for self-monitoring drug therapy;
 - g. Proper storage;
 - h. Prescription refill information;

i. Action to be taken in the event of a missed dose; and

j. Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(c) Alternative forms of patient information may be used to supplement patient counseling. Examples shall include written information leaflets, pictogram labels, or video programs.

(d) Patient counseling, as described above shall not be required for inpatients of penal institutions or inpatients of a hospital or long term care facility where other licensed health care professionals are authorized to administer the drugs and drug therapy reviews are conducted on a routine basis.

(e) Prospective drug use review, retrospective drug use review, and patient counseling shall be required for drugs dispensed by:

(1) Health maintenance organizations (HMO's);

(2) Mail order pharmacies;

(3) Hospital pharmacies providing outpatient prescription services; and

(4) Inpatients who are discharged with drugs.

(f) A pharmacist shall not be required to counsel a patient or agent when the patient or agent refuses such consultation. However, failure to document the patient's refusal of counseling shall imply that counseling was provided.

PART Ph 707 DISPOSAL AND DESTRUCTION OF CONTROLLED DRUGS

Ph 707.01 Controlled Drug Destruction. Any person authorized to possess controlled drugs and desiring to dispose of such drugs may request destruction of the drugs by the board or request an authorization from the board to destroy such drugs.

Ph 707.02 Request for Destruction.

(a) A request to destroy controlled drugs shall be in writing and signed by a duly authorized person as defined in (b) below. The itemized written request shall be conveyed to the board office and the destruction process shall not proceed until the authorization is received by the person who made the request.

(b) Personnel authorized to sign a request for controlled drug destruction shall include:

(1) Pharmacist-in-charge, as defined in RSA 318:1, X, practitioners or their designated agents;

(2) Administrators of health care institutions or their designated agent or agents;

(3) Agents of the superior court;

(4) County attorneys;

(5) Director, New Hampshire state police;

(6) Chiefs of local police departments; and

(7) Director, New Hampshire division of public health services or his/her designated agent(s).

(c) The written request shall not be required when a consultant pharmacist, acting as an agent of the pharmacy board, destroys controlled drugs in a licensed long-term care or specialized care facility.

Ph 707.03 Board Authorized Controlled Drug Destruction.

(a) A consultant pharmacist to a nursing home shall be designated an agent of the pharmacy board for the sole purpose of destroying controlled drugs at the licensed home or homes for which he or she serves as consultant by filing a written request at the board office, identified in Ph 103.03. The written request shall be on the licensed nursing home's letterhead, shall identify the pharmacist as the home's consultant pharmacist, and shall be signed by both the administrator of the nursing home and the consultant pharmacist. Once authorization is obtained:

(1) A record of the controlled drugs destroyed shall be made on form #Ph 558 obtained at the board office, identified in Ph 103.03; and

(2) Copies of form #Ph 558 shall be distributed as follows:

- a. The original shall be sent to the board office;
- b. A copy shall be maintained on the premises where the destruction occurred for a period of 4 years; and
- c. An optional copy retained by the agent making the destruction.

(b) The pharmacist-in-charge at a licensed hospital pharmacy shall be responsible for overseeing the destruction of controlled substances, in accordance with the procedures as set by the hospital's Hazardous Waste Disposal Committee and at no expense to the state of New Hampshire. The destruction of controlled substances shall be performed by a registered pharmacist, employed by the institution, and witnessed by a second licensed healthcare professional or registered technician as designated by the pharmacist-in-charge. The pharmacist-in-charge shall:

(1) Create a record of such controlled drugs destroyed made on federal form DEA 41 obtained from the board office, identified in Ph 103.03; and

(2) Distribute copies of form DEA 41 as follows:

- a. The original shall be sent to the board office; and
- b. A copy shall be retained in the hospital pharmacy where the destruction occurred for a period of 4 years.

(c) In a patient care area of the institution, partially used, patient-specific controlled substances may be destroyed by one licensed healthcare professional and witnessed by a designee of the pharmacist-in-charge as described in the written policies and procedures of the institution relative to the accountability and method of destruction of such drugs.

(d) In the interest of the health and safety of group home residents, the facility's consultant pharmacist(s) may remove from such group homes any discontinued, expired or otherwise unusable drugs.

(e) In order to remove the drugs referenced in (d) above, the consultant pharmacist shall:

(1) Notify the board that a request has been made by the facility, to the consultant pharmacist, for removal of drugs;

(2) Submit to the board a written request for removal of such drugs;

(3) File one copy of form Ph 516, issued by the board pursuant to (2) above, at the group home, including the following information:

a. Name and address of the group home;

b. Name of the consultant pharmacist;

c. Listing of drugs to be destroyed;

d. Date of removal of the drugs from the group home; and

e. The location where such drugs were removed to while awaiting destruction by a board of pharmacy inspector.

(4) Retain one copy with the drugs, which shall be removed to the consultant's place of practice.

(f) Upon receipt of the original of form Ph 516, a compliance investigator shall proceed to the consultant's place of practice to supervise the destruction of the drug.

Ph 707.04 Controlled Drug Destruction by the Board of Pharmacy.

(a) The destruction of controlled drugs by the board shall occur on the premises of the practitioner, institution or agency requesting the destruction. However, agents of the board shall remove from the premises any drug or drugs for destruction to be disposed of by incineration. Destruction shall be carried out by any person so designated as the authorized agent of the board provided that such agent as well as the person requesting destruction or his or her designee are present during the entire destruction process.

(b) The practitioner or person requesting destruction or their designee shall also be present and shall witness destruction of the controlled drugs.

(c) Witnesses may include:

(1) The practitioner, including a pharmacist;

(2) The administrator or assistant administrator;

(3) The director of nursing, nursing supervisor or charge nurse;

(4) An agent of the court;

(5) A law enforcement officer;

(6) The director, New Hampshire department of health and human services or his or her designated agent or agents; and

(7) A county attorney.

Ph 707.05 Record of Controlled Drug Destruction.

(a) A record of the drugs destroyed shall be made on federal form DEA-41, "Registrant's Inventory of Drugs Surrendered" in accordance with 21 CFR 1307.21, 22. This form may be obtained from the board office, identified in Ph 103.03 or from an office of the Drug Enforcement Administration.

(b) The data recorded on form DEA-41 shall include at least the:

- (1) Name, strength, and quantity of the drugs destroyed;
- (2) Date, time and place of destruction;
- (3) Manner of destruction; and
- (4) Signature and title of persons destroying and witnessing destruction of the controlled drugs.

(c) Copies of the form designated in Ph 707.05(a) shall be distributed as follows:

- (1) The original shall be maintained at the board office, identified in Ph 103.03; and
- (2) A copy retained on the premises of the practitioner, agency, court, or person requesting the destruction.

(d) A copy of the record of those drugs destroyed shall be maintained on the premises where the destruction occurred for a period of 4 years.

Ph 707.06 Exemption. Nothing contained in part Ph 707 shall require the board to destroy any drug if the board determines that to do so would impair law enforcement efforts or the health or safety of any person.

PART Ph 708 TERMINATION OF A PHARMACY OPERATION

Ph 708.01 Notification of Closing.

(a) Written notification to the board shall be filed at least 15 days prior to the date of the anticipated closing. This notice shall indicate the date of closing and the planned disposition of legend drugs including controlled substances and all records thereof.

(b) Written notification to DEA shall be filed at least 15 days prior to the date of the anticipated closing. Compliance with DEA instructions relative to closing procedures shall be required.

(c) At least 5 days prior to the anticipated closing a notice shall be conspicuously posted at the pharmacy indicating the date of closing and the future location of the prescription files. This notice shall be posted for a period of at least 30 days unless removed by the landlord or a new tenant.

Ph 708.02 Disposition of Drugs/Records.

(a) Security of the pharmacy shall be maintained while there is a supply of legend drugs including controlled substances on the pharmacy premises. Stable, unopened containers of legend drugs including controlled drugs may be returned by the pharmacy to the wholesaler/manufacturer.

(b) At the time of closing, the remaining supply of non-controlled prescription drugs may be sold or given to another pharmacy.

(c) At the time of closing, the remaining supply of controlled substances may be sold or given to another pharmacy provided that:

- (1) The transfer of schedule II substances shall comply with 21 CFR 1307.14 and 21 CFR 1305.06 by means of a properly executed federal DEA #222 Form;
- (2) The transfer of schedules III, IV, and V are made by invoice with copies to each party and the board; and
- (3) Prescription files, executed DEA #222 forms, biennial DEA inventories, applicable invoices, the balance of stock of all controlled substances, and the final printouts required by Ph 703.05(r)(2), shall be transferred as a package.

(d) If, in the interest of public health and safety, the board determines that after closure of the pharmacy a lack in the security, according to Ph 702.04, of the prescription drugs including controlled substances exists, the licensee shall immediately surrender to the board all prescription drugs including controlled substances and forms and invoices thereof. The drugs so held shall be inventoried, packaged, sealed and stored at the expense of the licensee in a place determined by the board to be appropriately secure. The licensee shall have 60 days after the effective date of the closing to make arrangements for the lawful sale or other disposition of these drugs. Lawful sale and/or disposition of these drugs shall be to a duly licensed person authorized to possess and store prescription drugs including controlled substances. Failing compliance within this 60-day period, such drugs shall then be surrendered to the board for destruction.

(e) Before disposing of any merchandise in the pharmacy, the owner and pharmacist-in-charge shall submit the licensed premises to an inspection by a representative of the board to certify that all prescription drugs including controlled substances have been secured.

Ph 708.03 Final Written Report. No later than 20 days after a pharmacy closing, the licensee shall:

- (1) Return the pharmacy permit to the board;
- (2) Notify the board that all signs and symbols indicating the presence of a pharmacy have been removed;
- (3) Notify the board that all labels and blank prescriptions have been destroyed;
- (4) Notify the board that the DEA license and all blank DEA #222 forms have been returned to the regional director of the DEA;
- (5) File with the board, a copy of the dated inventory of all controlled substances transferred including the name and address of the person(s) to whom these drugs and applicable records were transferred; and
- (6) In the case of an involuntary closing, file with the board the final disposition of the drugs as soon as possible after the transfer is made.

PART Ph 709 INSTITUTIONAL PRACTICES

Ph 709.01 Definitions.

(a) “Automated medication supply system” means an electronically controlled system that performs operations or activities relative to the storage and distribution of medications for administration and which collects, controls, and maintains all transaction information.

(b) “Electronic identifier”, for purposes of paragraph (a) above, means a unique security code or other identifier which specifically identifies the person entering information into a data processing system.

Ph 709.02 Licensing and Practice Standards.

(a) A pharmacy permit shall be required for each institution with an on-premise pharmacy. Such permit shall be issued to a pharmacist-in-charge, who shall be licensed in the state of New Hampshire. When an institution procures prescription drugs for its patients only on individual prescriptions for specific patients from an off-premise licensed pharmacy, the institution shall not be required to obtain a pharmacy permit.

(b) If an institution does not have a pharmacy on its premises, it may enter into an agreement with a pharmacy licensed to provide such services. Such agreement shall be in writing and shall state the policy and procedures as required by Ph 709. A copy of the agreement shall be made available by the consultant pharmacist to the board upon request. The consultant pharmacist shall be responsible for the maintenance of all records and the compliance with state and federal laws and rules governing the practice of pharmacy.

(c) An institutional license shall permit the pharmacy to dispense medications to in-patients of the institution, staff or employees of the institution, interim supplies of medication to outpatients in emergency situations and home infusion therapy to contractual patients not requiring hospitalization. If a pharmacist is on the premises, outpatient prescription services may be provided by the pharmacy, on a one-time, no-refill basis, to an ambulatory care patient and any patient who is being discharged with medications related to the patient's hospitalization. Labeling for all outpatient prescriptions shall be according to RSA 318:47-a and RSA 318-B: 11.

(d) Members of the board and/or their agents shall inspect the pharmacy, drug room/medication room and all areas or departments of the facility where drugs are stored, manufactured, compounded, dispensed or distributed to ensure:

(1) That adequate drug security and storage requirements are met;

(2) That proper records are maintained; and

(3) That the facility is in compliance with all local, state and federal drug and pharmacy laws and rules.

(e) Those facilities obtaining prescription drugs only on individual prescriptions for specific patients from an off-premise licensed pharmacy shall not be exempt from inspection.

(f) Each institution shall have a pharmacy and therapeutics committee or a comparable committee of its medical staff. This committee shall be composed of representatives of the medical staff and the pharmacist-in-charge, or a licensed staff pharmacist designated by the pharmacist-in-charge, and representatives of the administrative and nursing departments. The pharmacy representative shall be a voting member of the committee and the committee shall meet at least twice a year. The major functions of this committee shall be to establish the written policies and procedures governing the practice of pharmacy, use of drugs, drug specifications and drug distribution.

(g) An institutional pharmacy may dispense a generic or therapeutic equivalent that has been approved by the pharmacy and therapeutics committee or its equivalent only to in-patients of the institution, staff or employees (and their dependents) of the institution, or interim supplies of medication to outpatients in emergency situations.

(h) When applicable, the corporate officer, or the officer's replacement, who signs the pharmacy permit shall be held accountable, along with the pharmacist-in-charge, regarding compliance to federal, state, and local laws related to the practice of pharmacy. Both individuals shall be held accountable regarding compliance as required by the New Hampshire board of pharmacy or other governmental agency regarding the practice of pharmacy.

(i) When applicable, the corporate officer, or the officer's replacement, who signs the pharmacy permit, and the pharmacist-in-charge, shall comply with federal, state and local laws related to the practice of pharmacy.

Ph 709.03 Environment.

- (a) The institutional pharmacy shall be enclosed, lockable and alarmed;
- (b) The institutional pharmacy shall have adequate space necessary for the storage, compounding, labeling, dispensing and sterile preparation of drugs prepared in the pharmacy.
- (c) The institutional pharmacy shall be arranged in an orderly fashion and shall be kept clean.
- (d) A sink with hot and cold running water shall be available to all pharmacy personnel.
- (e) The institutional pharmacy shall have locked storage for schedule II controlled substances and other controlled drugs requiring additional security.
- (f) The institutional pharmacy shall have designated areas for the storage of flammable and caustic materials. Such areas shall meet the requirements set by local and state fire laws.
- (g) The institutional pharmacy shall have a designated area for the preparation of sterile products.

Ph 709.04 Drug Security.

- (a) Drugs stored in any area or department of the facility shall be plainly labeled and kept in a specifically designated, well-illuminated cabinet, closet or storage area and shall be accessible only to authorized personnel.
- (b) When controlled drugs are stored in authorized areas other than in the pharmacy, special locked storage for all controlled substances requiring additional security shall be used.
- (c) When using an automated medication supply system, the pharmacist-in-charge or designee shall have the responsibility for developing a secure system to assign, discontinue or change personnel access codes.
- (d) A pharmacist or registered pharmacy technician under the direction of a pharmacist shall visit and create a retrievable record, at least monthly, all areas or departments of the institution where drugs, biologicals, pharmaceutical chemicals or other pharmaceutical preparations are stored to ensure that they are properly labeled, have not reached their expiration date and show no signs of deterioration. Any substance not conforming to these standards shall be removed from stock.

(e) A retrievable record of each monthly inspection specified in (d) above shall be maintained in the pharmacy for at least 2 years and shall be available to the board upon request.

(f) The pharmacist-in-charge shall ensure that the areas specified in (d) above are in compliance with federal and state drug laws relative to security, drug distribution and product tampering.

(g) The pharmacist-in-charge shall develop a distribution system which shall prevent the illicit diversion of drugs.

(h) Discrepancies shall be reported to the pharmacy within 24 hours and resolved within 72 hours. Missing or unaccounted controlled drugs shall be reported to the NH board and Drug Enforcement Agency (DEA) as specified by 21 CFR § 1301.76-b.

(i) When an emergency drug kit other than regulated by Ph 705.03, containing controlled substances is opened, shift counts shall be done by the nursing staff on all controlled substances until resealed by a pharmacist.

Ph 709.05 Dispensing Practices.

(a) Drugs shall be dispensed only by or in the presence of and under the supervision of a pharmacist, or prescriber in compliance with local, state and federal pharmacy-related laws and rules. Upon the written order of a prescriber a nurse may leave a properly labeled container of any non-controlled drug at the patient's bedside. A licensed nurse shall not dispense or compound drugs except as permitted by RSA 318:42.

(b) The pharmacy shall dispense medications pursuant of an order from a prescriber. Drugs shall be provided to patients in institutions only on the order of a practitioner legally authorized to write prescriptions. No change in the order for drugs shall be made without the approval of a practitioner qualified to write prescriptions.

(c) Each order pursuant to (b) above shall include at least the:

- (1) Patient's name and location;
- (2) Date of the order;
- (3) Name and dosage of the drug;
- (4) Directions; and
- (5) Signature of the prescriber or licensed health care professional receiving the order.

(d) Written policies and procedures shall be adopted which establish the method utilized in the procurement, storage and distribution of drugs in all areas or departments of the facility, and which are consistent with state and federal pharmacy laws and rules.

Ph 709.06 Access to the Pharmacy.

(a) Only a pharmacist shall open and close the pharmacy. The pharmacist-in-charge of each institutional pharmacy shall establish written policies identifying specific situations when pharmacy technicians may be present in the pharmacy in the absence of a licensed pharmacist.

(b) In the absence of a pharmacist and in accordance with RSA 318:38,I licensed nurses, designated for this purpose by the pharmacist-in-charge, may obtain from the pharmacy or night cabinet such drugs as needed in an emergency when these drugs are not available in floor stock supplies.

(c) The authorized nurse may enter the pharmacy area and remove the following:

- (1) A drug in its original container or a drug prepackaged for use within the facility subject to these rules; or
- (2) An emergency supply of a drug from the original container to be administered to a specific patient.

(d) The authorized nurse shall leave a copy of the physician's order in the pharmacy or night cabinet and on a suitable form record the following:

- (1) Name and strength of the drug taken;
- (2) Dosage form taken;
- (3) Quantity taken;
- (4) Time and date of withdrawal;
- (5) Patient name and/or location, where applicable and; and
- (6) Nurse's signature.

(e) The nurse shall leave with the record the bulk container from which the medication was taken or a representative sample of the unit-dose medication.

Ph 709.07 Drug Control in Ambulatory Patient Treatment Areas.

(a) In the ambulatory patient treatment areas, a medical practitioner may dispense drugs for the immediate needs of the patient, not in excess of a 72-hour supply, except that, for Schedule II controlled substances, a maximum of 48-hour supply shall be allowed, if permitted by the institution. The drug container shall be properly labeled.

(b) If a licensed pharmacist is on the premises, that pharmacist may fill one time, full amount, non-refillable prescriptions for patients for medications related to the ambulatory patient treatment visit.

(c) A readily retrievable record shall be made of all administrations and dispensing of controlled drugs in the ambulatory patient area.

(d) This record shall include:

- (1) Name and address of the patient;
- (2) Name of the medical practitioner;
- (3) Name, strength and quantity of the drug(s);
- (4) Date of administration or dispensing; and
- (5) Signature or electronic identifier, as defined in Ph 709.01(b), of the agent removing the drug(s) from the inventory.

Ph 709.08 Investigational Drugs. Investigational drugs for research shall be used only under the supervision of the principal investigator and shall be approved by an appropriate medical staff committee. Such drugs shall be controlled by the pharmacy and shall be properly labeled. A central unit, which may be the pharmacy, shall be established where essential information on investigational drugs is maintained. Nurses shall be given basic pharmacologic information about the drug before administering.

Ph 709.09 Purchase of Drugs.

(a) The pharmacist-in-charge, with the consent of the institution's pharmacy and therapeutics committee or comparable committee of its medical staff shall be responsible for the quality of all drugs, biologicals and pharmaceutical chemicals.

(b) Purchasing of drugs, pharmaceuticals, biologicals, intravenous and irrigation fluids shall be subject to approval of the pharmacist-in-charge with the consent of the institution's pharmacy and therapeutic committee or comparable committee of its medical staff.

(c) Radiopharmaceuticals, blood products, radiopaque media and medical devices may be exempted from the approval and/or control of the pharmacist-in-charge by the institution's pharmacy and therapeutics committee.

PART Ph 710 ADMINISTRATIVE FINES

Ph 710.01 Liability for Administrative Fines. Persons subject to the disciplinary authority of the board and other persons subject to administrative fines or penalties under RSA 318:29, IV shall, at the discretion of the board, after notice and an opportunity to be heard, be assessed fines and/or penalties as authorized under RSA 318:29, IV.

Ph 710.02 Severity of Fine.

(a) The decision to impose a fine and the amount of such fine shall depend on:

- (1) The severity of harm to the public posed by the violation(s);
- (2) The number of concurrent and/or repeated violations; and
- (3) The frequency of violations committed by the particular licensee, permit holder, or other person.

(b) When no violation of the same type has occurred within the 5 years preceding the board's notice to the respondent, the fine assessed shall not exceed \$1,000 per violation upon the licensee and/or \$2,000 per violation upon the permit holder.

(c) When a single disciplinary infraction of the same type has occurred within the 5 years preceding the board's notice to the licensee, the fine assessed shall not exceed \$2,000 per violation upon the licensee and/or \$3,000 per violation upon the permit holder.

(d) When more than one disciplinary infraction of the same type has occurred within the 5 years preceding the board's notice to the licensee, the fine assessed shall not exceed \$3,000 per violation upon the licensee and/or \$5,000 per violation upon the permit holder.

(e) In the case of continuing violations, a separate fine shall be assessed for each day the violation continues, but the total amount of the fine and the licensee's promptness and cooperativeness in ceasing the prohibited conduct in question shall be considered in assessing the daily fines.

(f) In all cases, the board shall consider:

- (1) The nature of the offense;
- (2) The purpose of the rule or statute violated;
- (3) The licensee's state of mind at the time the offense occurred;
- (4) The potential harm to the public health;
- (5) The deterrent effect upon other practitioners;
- (6) The licensee's willingness to cooperate with the board;
- (7) The cost to the board of any formal disciplinary hearings which were necessary;
- (8) The licensee's acknowledgment of his or her wrongdoing; and
- (9) The nature of any other disciplinary sanctions imposed as a result of the offense in question.

CHAPTER Ph 800 PHARMACY TECHNICIANS

PART Ph 801 PURPOSE AND SCOPE

Ph 801.01 Purpose and Scope. The provisions of this chapter shall apply to, and impose duties upon, all pharmacy technicians holding registrations issued by the board.

PART Ph 802 DEFINITIONS

Ph 802.01 Definitions. Except where the context makes another meaning manifest, the following definitions shall apply:

(a) "Registered pharmacy technician" means a person employed by a pharmacy who may assist in performing, under the supervision of a licensed pharmacist, manipulative, nondiscretionary functions associated with the practice of pharmacy and other such duties and subject to such restrictions as the board has specified.

PART Ph 803 REGISTRATION

Ph 803.01 Application.

(a) No person shall perform the functions or duties of a pharmacy technician unless such person is registered by the board.

(b) Application form PT-1 for registration of pharmacy technicians in New Hampshire may be obtained from and shall be filed at the office of the board, identified in Ph 103.03.

(c) An applicant for registration as a registered pharmacy technician shall meet the following requirements:

- (1) Be at least 18 years of age or have a high school or equivalent diploma, or be working to

achieve a high school or equivalent diploma;

(2) Be of good moral character;

(3) Shall not have been convicted of a drug-related felony or admitted to sufficient facts to warrant such findings; and

(4) Shall have training or experience as determined by the pharmacist-in-charge.

(d) Applicants for registration shall submit an application form PT-1 for registration to the board that contains the following:

(1) Name, residence address, home telephone number and social security number of the applicant;

(2) Date and place of birth of the applicant;

(3) Name of current employer and address of employment site;

(4) Record of convictions of violations of federal, state or local drug or pharmacy related laws or regulations;

(5) Any felony convictions;

(6) Applicant's signature and date; and

(7) The prescribed fee which shall be \$25.

PART Ph 804 REGISTRATIONS – CHANGES IN SUPPORTING DATA

Ph 804.01 Reporting Changes.

(a) The person to whom a pharmacy technician registration has been issued shall, within 15 days of change of address or location of employment, notify the board of such changes.

(b) The notice shall contain:

(1) Name of registrant;

(2) Address of the registrant including old and new, if applicable;

(3) Registrant's registration number; and

(4) Name of the pharmacy where employed including former and current, if applicable.

PART Ph 805 REVOCATION AND DENIAL

Ph 805.01 Effect of Revocation and Denial.

(a) The board shall refuse to issue a registration or, after notice and hearing, shall revoke a registration whenever the board finds by the preponderance of the evidence any of the following:

- (1) That the applicant does not possess good moral character;
- (2) That the applicant, or registrant, has willfully violated any of the provisions of RSA 318; RSA 318-B and/or the board's Code of Administrative Rules;
- (3) That the applicant has been convicted of a felony or a misdemeanor resulting from a violation of any federal, state, or local drug or pharmacy-related law, rule or regulation;
- (4) That the applicant has attempted to obtain a pharmacy technician registration by fraudulent means;
- (5) That the applicant is unable to engage in the performance of pharmacy technician functions with reasonable skill and safety by reason of illness, inebriation, misuse of drugs, narcotics, alcohol, chemicals or any other substance, or as a result of any mental or physical condition;
- (6) The suspension, revocation, or probation by another state of the applicant's license, permit, or registration to practice as a pharmacy technician;
- (7) That the applicant refused to appear before the board after having been ordered to do so in writing; or
- (8) That the applicant made any fraudulent or untrue statement to the board.

(b) The pharmacist-in-charge shall notify the board, in writing, within 7 calendar days after becoming aware that a pharmacy technician has adulterated, abused, stolen or diverted drugs.

PART Ph 806 RENEWAL OF REGISTRATIONS

Ph 806.01 Renewal Registrations Required. All pharmacy technician registrations shall expire annually on March 31.

Ph 806.02 Renewal Application Where Obtained and Filed. Applications for the renewal of a registration for a pharmacy technician may be obtained from, and shall be filed at the office of the board, identified in Ph 103.03.

Ph 806.03 Renewal Application Contents and When Filed. Renewal applications shall be filed with the board in accordance with the following:

(a) Applications for renewal of a registration of a pharmacy technician shall be made on Pharmacy Technician Renewal Form PT-2.

(b) Each applicant shall provide the following on Form PT-2 regarding himself/herself:

- (1) Name, residence address, home telephone number;
- (2) Original registration number;

- (3) Social security number and date of birth;
 - (4) Name of current employer and address of employment site;
 - (5) Record of convictions of violations of federal, state or local drug or pharmacy related laws or regulations; and
 - (6) Applicant's signature and date.
- (c) The application and the prescribed fee

PART Ph 807 PHARMACY TECHNICIANS – STANDARDS OF PRACTICE

Ph 807.01 Responsibilities and Duties. Persons subject to these rules shall comply with the following:

- (a) It shall be the responsibility of the pharmacist-in-charge to identify pharmacy technicians and to assure that such persons are registered with the board as pharmacy technicians within 30 days of employment.
- (b) All pharmacy technicians shall wear a name tag, identifying them as a "Pharmacy Technician", while on duty.
- (c) The pharmacist on duty shall determine the duties of the pharmacy technician based upon the needs of the pharmacy. Pharmacy technicians shall be limited to performing tasks in the preparation of legend drugs and devices and to provide nonjudgmental technical support services, as defined in Ph 807.01.
- (d) Pharmacy technicians shall not:
 - (1) Accept an original telephone order for a prescription;
 - (2) Accept a refill authorization communicated by telephone directly from a practitioner's office;
 - (3) Evaluate patient profiles relative to prospective drug review according to Ph 706.02;
 - (4) Communicate, orally or in writing, any medical, therapeutic, clinical, or drug information, or any information recorded on a patient profile that requires professional judgment or otherwise perform patient counseling as required in Ph 706.
- (e) The pharmacist shall verify and confirm the correctness, exactness, accuracy and completeness of the acts, tasks, and functions undertaken by the pharmacy technician who assists the pharmacist in the practice of pharmacy.

CHAPTER Ph 900 MAIL-ORDER PHARMACY

PART Ph 901 PURPOSE AND SCOPE

Ph 901.01 Scope. The provisions of this chapter shall apply to, and impose duties upon, all mail-order pharmacies holding registrations issued by the board.

PART Ph 902 DEFINITIONS

Ph 902.01 “Mail-order pharmacy” means “mail-order pharmacy” as defined in RSA 318:1, VII-b, namely, “a pharmacy that is located in a state of the United States, other than this state, whose primary business is to dispense a prescription drug or device under a prescription drug order and to deliver the drug or device to a patient, including a patient in this state, by the United States mail, a common carrier, or a delivery service. Mail-order pharmacies include, but are not limited to, pharmacies that do business via the Internet or other electronic media.”

PART Ph 903 REGISTRATION

Ph 903.01 Application.

(a) No person shall conduct or operate a mail-order pharmacy located outside of this state by delivering in any manner prescription drugs or prescription devices into this state unless such pharmacy is registered in New Hampshire and a permit has been issued by the New Hampshire board of pharmacy.

(b) Application form MO-1, “Registration of Mail-order Pharmacy,” may be obtained from and shall be filed at the office of the board, identified in Ph 103.03.

(c) Applicants for registration as a mail-order pharmacy shall submit a completed MO-1 that contains the following information:

- (1) Name, address, telephone number and Internet address, if applicable, of the pharmacy;
 - (2) The names, addresses and titles of all principal corporate officers, if incorporated and if unincorporated, partners or owners of the pharmacy;
 - (3) If a corporation, a certificate of incorporation from the state in which incorporated;
 - (4) If a limited liability company, partnership or sole proprietorship, a tax ID number;
 - (5) The name and state license number of the pharmacist-in-charge of the location listed in (1) above;
 - (6) A copy of the pharmacy’s current license, permit, or registration certificate used by the regulatory or licensing agency of the state in which the pharmacy is located, as well as a copy of the current DEA registration, if applicable;
 - (7) A copy of the most recent inspection report conducted by the state in which the pharmacy is located;
 - (8) A list of any and all Internet websites from which the mail-order pharmacy solicits business; and
 - (9) Signature of the pharmacist-in-charge and date.
- (d) As attachments to the completed MO-1, the applicant shall provide the following:
- (1) One of the following:

a. Verified Internet Pharmacy Practice Sites[™] accreditation from the National Association of Boards of Pharmacy[®]; or

b. The following materials:

1. At least 2 photographs of the actual existing exterior, including the pharmacy signage, of the building in which the pharmacy will be or is currently located;
2. At least 2 photographs of the prescription department as viewed by an approaching patron;
3. At least 4 photographs of the prescription department as viewed from the interior, showing the prescription compounding area, refrigerator, water facilities and pharmaceutical inventory storage area; and
4. Scaled drawings of the pharmacy and drug storage area;

(2) A prescription label, containing the name, address and phone number of the pharmacy, that would be used on finished prescription products mailed to NH residents;

(3) A sample copy of a printed patient medication profile that shall include the following information:

- a. Name and address of the patient;
- b. Name, address and DEA registration number of the prescriber;
- c. Name, strength and quantity of drug dispensed;
- d. Assigned prescription number;
- e. Date of original filling; and
- f. Date of refill(s); and

(4) The prescribed fee which shall be \$300.

(e) Any person or pharmacy whose pharmacy business fits the definition of a mail-order pharmacy and delivers prescription drugs or prescription devices to New Hampshire residents from more than one out-of-state pharmacy shall register each such pharmacy separately.

PART Ph 904 REGISTRATIONS – CHANGES IN SUPPORTING DATA

Ph 904.01 Reporting Changes.

(a) The mail-order pharmacy to which a registration has been issued shall, within 30-days of any change of information supplied in the original application, notify the board.

(b) The notice required pursuant to (a) above shall contain:

- (1) Current New Hampshire registration number of the pharmacy;
- (2) Name of the pharmacy, old and new, if applicable;
- (3) Address of the pharmacy, old and new, if applicable;

(4) Name of the pharmacist-in-charge, old and new, if applicable; and

(5) Name(s), addresses and titles, of new corporate officers, or partners, or owners.

(c) A new registration shall be required for a change of ownership of an established pharmacy to a successor business entity which results in a change in the controlling interest in the pharmacy.

PART Ph 905 REVOCATION AND DENIAL

Ph 905.01 Effect of Revocation and Denial.

(a) The board may refuse to issue a registration or may, after notice and opportunity for a hearing, revoke a registration whenever the board finds out that a mail-order pharmacy, its pharmacist-in-charge, owner(s) or corporate officer(s) has:

(1) Made a materially false representation or withheld material information in connection with obtaining its registration;

(2) Been found guilty of any felony in connection with the practice of pharmacy or distribution of drugs;

(3) Made false representations in connection with the practice of pharmacy that endanger or are likely to endanger the health or safety of the public, or that defraud any person;

(4) Failed to comply with RSA 318:37, II, the provisions of Ph 900, or both;

(5) Based on an investigation of a complaint resulting from the dispensing of prescription drugs or prescription devices to a resident of New Hampshire been found to be negligent:

a. By the board of pharmacy of the state in which the pharmacy is located; or

b. By the New Hampshire board of pharmacy if the board of pharmacy of the state where the pharmacy is located failed to initiate an investigation of such complaint within 45-days after referral of the complaint from the New Hampshire board of pharmacy; or

(6) Been found guilty of any violation of federal, state or local drug law or have entered into any agreement to resolve violations of such.

(b) A mail-order pharmacy shall notify the board within 5-days of any order or decision by a board of pharmacy, or any other state or federal agency, imposing disciplinary action on the pharmacy. Notwithstanding the provisions of paragraph (a) above, if the license, permit or registration in the state where the pharmacy is located, is suspended or revoked, then the pharmacy's registration in New Hampshire shall, after notice and opportunity for hearing, be suspended or revoked for the same period of time.

PART Ph 906 RENEWAL OF REGISTRATIONS

Ph 906.01 Renewal Registrations Required. All mail-order pharmacy registrations shall expire annually on March 31.

Ph 906.02 Renewal Application Where Obtained and Filed. Applications for the renewal of a registration for a mail-order pharmacy may be obtained from, and shall be filed at that office of the board, identified in Ph 103.03.

Ph 906.03 Renewal Application Contents and When Filed. Renewal applications shall be filed with the board in accordance with the following:

(a) Applications for renewal of a registration for a mail-order pharmacy shall be made on form MO-2 "Application for Renewal of Registration for Mail-order Pharmacy;"

(b) Each applicant shall provide the following on or as an attachment to form MO-2 no later than March 31:

(1) Name, address, telephone number and Internet address, if applicable, of the pharmacy

(2) The name of the pharmacist-in-charge;

(3) The names, corporate or business addresses and titles, of all principal corporate officers if incorporated, or all partners or owners of the pharmacy if not incorporated; and

(4) A copy of the current license, permit, or registration certificate used by the regulatory or licensing agency of the state in which the pharmacy is located, as well as a copy of the current DEA registration, if applicable, shall be submitted with the renewal application;

(5) The application and the prescribed fee of \$250; and

(6) Signature of the pharmacist-in-charge and date; and

(c) Renewal applications received after March 31 shall be subject to a \$25 administrative late fee and no registration shall be issued until all fees are paid in full.

PART Ph 907 CONDITIONS OF REGISTRATION

Ph 907.01 Compliance. As conditions of registration, the mail-order pharmacy shall:

(a) Maintain at all times a valid unexpired permit, license, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident;

(b) Maintain in readily retrievable form, records of legend drugs, devices, or both dispensed to New Hampshire patients;

(c) Supply upon request, any and all information needed by the board to carry out its responsibilities under the statutes and rules pertaining to mail-order pharmacies;

(d) Provide for a toll-free telephone communication consultation between New Hampshire patients and a pharmacist at the mail-order pharmacy who has access to the patient's records, and ensure that such toll-free telephone number(s) shall be placed upon the label affixed to each prescription container;

(e) Provide to the board, upon request, a copy of the policies and procedures governing;

(1) Normal delivery protocols and times;

- (2) Any special packaging or procedures used in delivering temperature-sensitive drug products;
 - (3) The procedure to be followed if the patient's medication is not available at the mail-order pharmacy, or if delivery will be delayed beyond the normal delivery time;
 - (4) The procedure to be followed upon receipt of a prescription for an acute illness, which shall include a procedure for delivery of the medication to the patient from the mail-order pharmacy at the earliest possible time, such as courier delivery, or an alternative that assures the patient the opportunity to obtain the medication at the earliest possible time; and
 - (5) The procedure to be followed when the mail-order pharmacy is advised that the patient's medication has not been received within the normal delivery time and that the patient is out of medication and requires interim dosage until mail prescription drugs become available.
- (f) All finished prescription products shipped to New Hampshire residents shall be shipped in tamper-evident envelopes or boxes;
- (g) A mail-order pharmacy shall not dispense or sell to the public, any drug which is adulterated or misbranded.
- (h) A mail-order pharmacy shall supply, upon request from the board, a statement of origin of any specific drug dispensed to a New Hampshire resident;
- (i) Any mail-order pharmacy shipping finished prescription products into the State of New Hampshire shall use the address, but without the name of the pharmacy, on file with the New Hampshire board of pharmacy as the return address on the labels of any package shipped into the State of New Hampshire. The return address shall be placed on the package in a clear and prominent manner.

CHAPTER Ph 1000 EMERGENCY CONTRACEPTION

PART Ph 1001 COLLABORATIVE PRACTICE FOR EMERGENCY CONTRACEPTION

Ph 1001.01 Collaborative Practice Authorized. Notwithstanding any other provisions of law, a licensed pharmacist who has completed the training required in Ph 1001.02 may initiate emergency contraception drug therapy in accordance with the provisions of Ph 1001.

Ph 1001.02 Education and Training.

- (a) Any pharmacist initiating emergency contraception drug therapy shall complete a minimum of 0.2 CEU's, 2 didactic/live hours, of approved training and education prior to participating in the delivery of emergency contraception drug therapy.
- (b) Programs for training and education, referenced in (a) above shall be:
 - (1) Accredited by the Accreditation Council for Pharmacy Education (ACPE); or
 - (2) Approved by the board of pharmacy according to Ph 403.01(b).
- (c) Programs for training and education, as referenced above, shall include study materials and instruction in the following content areas:

- (1) Mechanisms of action, contraindication, drug interaction, and monitoring of emergency contraception drug therapy;
- (2) Current standards for prescribing emergency contraception drug therapy;
- (3) Identifying indications for use of emergency contraception drug therapy;
- (4) Interviewing patient to establish need for emergency contraception drug therapy;
- (5) Counseling patient regarding the safety, efficacy and potential adverse effects of drug products for emergency contraception;
- (6) Evaluating patient's medical profile for drug interaction;
- (7) Referring patient follow-up care with primary healthcare provider;
- (8) Informed consent;
- (9) Record management;
- (10) Management of adverse events, including identification, appropriate response, documentation and reporting;
- (11) Management and response to negative public opinion; and
- (12) Medical/forensic implications of sexual attack.

Ph 1001.03 Emergency Contraception Collaborative Agreement.

(a) Each arrangement between a licensed pharmacist and an authorized prescriber relating to the distribution to a patient of emergency contraception drugs shall be documented in a signed collaborative agreement in accordance with form Ph EC-1, which may be obtained from the office of the board identified in Ph 103.03.

(b) By signing the collaborative agreement, which may be modified according to the authorized practitioner, both the pharmacist and the authorized prescriber agree and acknowledge that:

- (1) The licensed pharmacist shall provide the patient with drug information concerning dosage, potential adverse side effects, and follow-up contraceptive care;
- (2) The collaborative agreement shall be effective for a period of 2 years unless rescinded in writing earlier by either the pharmacist or the authorized prescriber, with written notice to the other, or unless the board of pharmacy invalidates the agreement or changes the terms of the agreement;
- (3) At the time the collaborative agreement expires or is rescinded, the licensed pharmacist shall not have authority to dispense emergency contraceptives until another collaborative agreement with an authorized prescriber is completed;
- (4) Each drug therapy prescription authorized by the prescriber and dispensed by the pharmacist shall be documented in a patient profile; and
- (5) No refills shall be permitted and the pharmacist shall not be authorized to provide a written, oral or electronic prescription enabling the patient to further obtain emergency contraception pursuant to the patient's immediate receipt of drug therapy.

(c) Additionally, the licensed pharmacist and the authorized prescriber shall include in the collaborative agreement the following:

- (1) The name, address, phone number and signature of the licensed pharmacist;
- (2) The name, address, phone number and signature of the authorized prescriber;
- (3) A statement indicating the purpose of the collaborative agreement is to permit emergency contraception drug therapy and to ensure that the patient receives appropriate information from the licensed pharmacist regarding the drug therapy;
- (4) The procedures to be followed by the licensed pharmacist when the patient requests drug therapy, including any applicable referrals;
- (5) Any limitation agreed upon by both the licensed pharmacist and the authorized prescriber including, but not limited to, approved drugs that may not be dispensed to the patient;
- (6) A statement that the label placed on the drug therapy product shall contain the names of both the pharmacist and the authorized prescriber of this agreement;
- (7) An informed consent format to be used by the licensed pharmacist to inform the patient about the emergency contraception drug therapy; and
- (8) A patient assessment format for each patient obtaining emergency contraception drug therapy shall be completed and signed by the licensed pharmacist on form Ph EC-3, which may be obtained from the office of the board identified in Ph 103.03.

(d) The informed consent referenced in (c)(7) above, shall be signed by both the licensed pharmacist and the patient on form Ph EC-2, which may be obtained from the office of the board identified in Ph 103.03.

Ph 1001.04 Informed Consent.

(a) The licensed pharmacist shall provide the patient with an informed consent form, in accordance with form Ph EC-2, which may be obtained from the office of the board identified in Ph 103.03.

(b) The informed consent form shall include at least the following:

- (1) The indications for use of emergency contraception;
- (2) The mechanism of action of the medication;
- (3) The appropriate method for taking the medication;
- (4) The possible reactions after taking the medication; and
- (5) The circumstances that may require follow-up with a physician.

(c) After the patient has read, and/or reviewed with the licensed pharmacist, the statements specified on the informed consent form, both the patient and the licensed pharmacist shall sign and date the form.

Ph 1001.05 Patient Assessment.

(a) The licensed pharmacist shall perform a patient assessment, in accordance with form Ph EC-3, which may be obtained from the office of the board identified in Ph 103.03.

(b) The patient assessment form shall include at least the following;

- (1) Patient's name and address;
- (2) Patient's date of birth;
- (3) Personal information which requires the use of emergency contraception; and
- (4) Determination of any known allergies to medications/drugs.

Ph 1001.06 Provision of Standardized Fact Sheet Required.

(a) For each emergency contraception drug therapy initiated pursuant to this chapter, the pharmacist shall provide the recipient of the emergency contraceptive drug with a standardized fact sheet developed by the board that includes at least the following:

- (1) The indications for use of the drug;
- (2) The appropriate method for using the drug;
- (3) The need for medical follow-up and referral information; and
- (4) Information on sexual assault and referral information.

(b) A copy of the standardized fact sheet Ph EC-4 may be obtained from the office of the board identified in Ph 103.03.

Ph 1001.07 Records to be Kept. The following completed forms shall be maintained for 4 years at the dispensing pharmacy where emergency contraception drug therapy was provided:

- (a) Collaborative Agreement (Ph EC-1), or a copy thereof, in effect during the time emergency contraception drug therapy was delivered to specific patients at that location;
- (b) Informed Consent (Ph EC-2), patient specific forms; and
- (c) Patient Assessment (Ph EC-3) forms for each patient.

Ph 1001.08 Confidentiality. Nothing in this chapter shall affect the provisions of law relating to maintaining the confidentiality of medical records.

CHAPTER Ph 1100 COLLABORATIVE PHARMACY PRACTICE

PART Ph 1101 PURPOSE AND SCOPE

Ph 1101.01 Purpose. The purpose of this chapter is to implement and regulate collaborative pharmacy practice as a means to make the provision of certain aspects of health care more efficient, less costly, and provided in a more timely manner.

Ph 1101.02 Scope. These rules shall regulate collaborative pharmacy practice only in the following institutions where the practice is permitted pursuant to RSA 318:16-a, III(a) – (d), namely:

- (a) Hospitals;
- (b) Long-term care facilities;
- (c) Licensed inpatient or outpatient hospice settings; and

(d) Ambulatory care clinics with onsite supervision by the attending practitioner and with a collaborating pharmacist who has no connection to any onsite retail pharmacy.

PART Ph 1102 DEFINITIONS

Ph 1102.01 “Attending practitioner” means “attending practitioner” as defined in RSA 318:1, XXV, namely, “the physician or advanced registered nurse practitioner who has the primary responsibility for the treatment and care of the patient.”

Ph 1102.02 “Collaborative pharmacy practice” means “collaborative pharmacy practice” as defined in RSA 318:1, XXV, namely, “the practice of pharmacy whereby one or more pharmacists jointly agree, on a voluntary basis, to work in conjunction with one or more attending practitioners under written protocol whereby the collaborating pharmacist or pharmacists may perform medication therapy management authorized by the attending practitioner or practitioners under certain specified conditions and limitations.”

Ph 1102.03 “Collaborative pharmacy practice agreement” means “collaborative pharmacy practice agreement” as defined in RSA 318:1, XXVII, namely, “a written and signed specific agreement between a pharmacist, an attending practitioner, and the patient or patient's authorized representative who has granted his or her informed consent, that provides for collaborative pharmacy practice for the purpose of medication therapy management for the patient.” For purposes of these rules, the term includes each protocol developed pursuant to RSA 318:16-a, II(a).

Ph 1102.04 “Medication therapy management” means “medication therapy management” as defined in RSA 318:1, XXVIII, namely, “the review of medication therapy regimens of patients by a pharmacist for the purpose of evaluating and rendering advice to a practitioner, or evaluating and modifying the medication regimen in accordance with the collaborative pharmacy practice agreement” and is limited to:

(a) Implementing, modifying, and managing medication therapy according to the terms of the collaborative pharmacy practice agreement;

(b) Collecting and reviewing patient histories within the context of needs for pharmacy practice;

(c) Obtaining and checking vital signs, such as pulse, temperature, blood pressure, and respiration;

(d) Ordering laboratory tests as specifically set out in the collaborative pharmacy practice agreement between the pharmacist and the attending practitioner that are specific to the medication or protocol-driven;

(e) Formulating a medication treatment plan that will be shared with the patient's attending practitioner;

(f) Monitoring and evaluating the patient's response to therapy, including safety and effectiveness;

(g) Performing a comprehensive medication review, in conjunction with the attending practitioner, to identify, resolve, and prevent medication-related problems, including adverse drug events;

(h) Documenting the care delivered and, if applicable, communicating essential information to the patient's other health care providers; and

(i) Providing education and training designed to enhance patient understanding and the appropriate use of his or her medications.

PART Ph 1103 COLLABORATIVE PHARMACIST QUALIFICATIONS AND APPLICATION

Ph 1103.01 Qualifications.

(a) A pharmacist who seeks to engage in collaborative practice shall meet the requirements of:

(1) RSA 318:16-a, I(a) relative to licensure in New Hampshire;

(2) RSA 318:16-a, I(b) relative to professional liability insurance coverage;

(3) RSA 318:16-a, I(c) relative to education or experience;

(4) RSA 318:16-a, I(d) relative to completion of continuing education in any of the subjects or activities listed in RSA 318:1, XXVIII, (a) – (i); and

(5) RSA 318:16-a, I(e) relative to administration of drugs by injection, if the pharmacist will administer drugs in that way.

(b) A pharmacist who seeks to engage in collaborative practice that includes the administration of vaccines shall hold current basic or higher certification in cardiopulmonary resuscitation (CPR) from the American Heart Association, the American Red Cross, or from another organization or entity that is nationally-recognized as an issuer of such certifications.

Ph 1103.02 Application.

(a) A pharmacist who seeks to engage in collaborative practice in one of the settings allowed under RSA 318:16-a, III, shall provide the following on or with a “Collaborative Pharmacist Application”:

(1) The pharmacist’s name and license number;

(2) The pharmacist’s business and home addresses;

(3) A certificate of insurance from the pharmacist’s professional liability carrier indicating that the pharmacist maintains insurance coverage that complies with RSA 318:16-a, I(b);

(4) A list of all continuing education courses that address the continuing education requirement stated in Ph 1103.01(a)(4);

(5) A copy of the CPR certification that complies with the requirements of Ph 1103.01(b);

(6) Identification of each practice setting in which the pharmacist intends to practice, including the name and address of each such institution;

- (7) If intending to administer drugs by injection, a certificate of completion of a training program that meets the requirements of RSA 318:16-a, I(e);
 - (8) An indication that the information provided on or with the application is true, correct, and complete to the best of the pharmacist's knowledge and belief; and
 - (9) The signature of the pharmacist and the date signed.
- (b) After receipt of a "Collaborative Pharmacist Application" the board's staff shall review it for any apparent errors or omissions and inform the applicant in writing if any are found. If informed of errors or omissions, the pharmacist shall correct the error or provide the missing application materials within 30 days of such notification being sent.
- (c) Each completed "Collaborative Pharmacist Application" shall be reviewed by the board at the next regular meeting that occurs at least 14 days after the application has been determined by board staff to be without apparent errors or omissions.
- (d) The board shall approve a "Collaborative Pharmacist Application" if the applicant meets the requirements of RSA 318:16-a, I and these rules or shall deny the "Collaborative Pharmacist Application" if any such requirement has not been met. The board shall notify the pharmacist in writing as soon as practicable following its decision.

PART Ph 1104 COLLABORATIVE PRACTICE AGREEMENTS AND PRACTICE THEREUNDER

Ph 1104.01 Collaborative Practice Agreements.

- (a) Each protocol developed pursuant to a collaborative practice agreement shall include all the elements specified in RSA 318:16-a, II(a)(1) – (6).
- (b) Each collaborative practice agreement, including each protocol developed pursuant thereto, shall be signed by the pharmacist, attending practitioner, and then the patient or the patient's authorized representative before it is put into effect. The signature of the patient or the patient's authorized representative shall be the last to be obtained.
- (c) The pharmacist shall maintain at the pharmacist's place of practice a copy of each collaborative practice agreement, including each protocol developed pursuant thereto, to which the pharmacist is a party.
- (d) The document referred to in (c) above shall be available for inspection and review by the board or its agents at any time during the pharmacist's usual or actual hours of practice.
- (e) If the pharmacist is the person who secures the patient or patient's authorized representative's signature on the collaborative practice agreement and informed consent form required pursuant to Ph 1104.02(b), the pharmacist shall provide the attending practitioner with a copy of the fully executed agreement as soon as practicable but in no case later than 24 hours after the patient or patient's authorized representative signs.

Ph 1104.02 Informed Consent of Patient or Patient's Authorized Representative.

- (a) Prior to requesting that the patient or the patient's authorized representative sign the collaborative practice agreement, the pharmacist shall ensure that:

- (1) A copy of the agreement, including each protocol developed pursuant thereto, has been provided with sufficient time for the documents to be reviewed;
 - (2) The patient or the patient's authorized representative has an opportunity to have any questions regarding such documents and their implementation answered to their satisfaction;
 - (3) All benefits and risks accruing under the agreement are fully explained to the patient or the patient's authorized representative;
 - (4) The patient or the patient's authorized representative understands that he or she may decline to participate or withdraw from the agreement at any time; and
 - (5) The patient or the patient's authorized representative is capable of providing informed consent.
- (b) Informed consent shall be evidenced by a signed informed consent form that complies with the policies and procedures of the institution in which the collaborative practice agreement will be implemented.

Ph 1104.03 Practice Under a Collaborative Practice Agreement.

(a) Practice by a pharmacist under a collaborative practice agreement shall not be delegable but shall be performed only by the pharmacist who is a party to the agreement.

(b) Prior to initiation of medication therapy management for a patient, the pharmacist shall review and confirm the patient's:

- (1) Name;
- (2) Gender, and if female, pregnancy and lactation status;
- (3) Date of birth;
- (4) Height and weight;
- (5) Diagnosis, through consultation with the attending practitioner;
- (6) Medication history;
- (7) Prior lab values;
- (8) Known allergies; and
- (9) Emergency contact information.

(c) The pharmacist shall review the collaborative practice agreement and each protocol developed pursuant thereto so as to determine whether changes should be made to reflect the standard of care. If such a review reveals that a change should be made, the pharmacist shall inform the attending practitioner and the patient or the patient's authorized representative.

(d) Nothing in this chapter shall be construed to prohibit an authorized pharmacist from participating in medication therapy management by protocol or policy approved by the medical staff of the hospital.

CHAPTER Ph 1200 CENTRAL PRESCRIPTION PROCESSING

PART Ph 1201 PURPOSE AND SCOPE

Ph 1201.01 Purpose. The purpose of this chapter is to set forth the requirements, limitations, and prohibitions for pharmacies that engage in central prescription processing so as to ensure that, for the protection of the public, all central prescription processing activities regulated by the board are performed in compliance with applicable state law and rules by those who are licensed by the board.

Ph 1201.02 Scope. This chapter shall apply to all persons whose activities come under the jurisdiction of the board and who engage in central prescription processing activities.

PART Ph 1202 DEFINITIONS

Ph 1202.01 “Central fill pharmacy” means a licensed pharmacy, in this or any other state, district or commonwealth of the United States, engaging in central prescription handling by filling, refilling, or both, prescriptions including the preparation, packaging, and labeling of the medication.

Ph 1202.02 “Central prescription processing” means “central prescription processing” as defined in RSA 318: 1, XXIII, namely, “the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order or to perform processing functions, such as dispensing, drug utilization review, claims adjudication, refill authorizations, and therapeutic interventions.”

Ph 1202.03 “Central processing pharmacy” means a licensed pharmacy, in this or any other state, district or commonwealth of the United States, that engages in prescription review by performing functions that include but is not limited to:

- (a) Data entry;
- (b) Prospective drug review;
- (c) Refill authorizations;
- (d) Interventions;
- (e) Patient counseling;
- (f) Claims submission;
- (g) Claims resolution; and
- (h) Adjudication.

Ph 1202.04 “Claims adjudication” means the process by which a prescription is submitted and processed through a third-party payor.

Ph 1202.05 “Dispensing pharmacy” means a licensed pharmacy, in this or any other state, district or commonwealth of the United States, that receives the processed prescription, the filled or refilled prescription, or both, for dispensing to the patient or to the patient’s authorized representative and providing patient counseling as required.

Ph 1202.06 “Intake pharmacy” means a licensed pharmacy, in this or any other state, district or

commonwealth of the United States, that receives the patient's or prescribing practitioner's request to fill or refill a prescription, including a central processing pharmacy or a central fill pharmacy, as defined below, if the prescription was transmitted by the prescribing practitioner directly to such pharmacy or if the patient requested the refill from that pharmacy.

PART Ph 1203 CENTRAL PRESCRIPTION PROCESSING

Ph 1203.01 General Requirements for Engaging in Central Prescription Processing. A pharmacy may perform or outsource central prescription processing and handling services provided that:

(a) All pharmacies involved in the transactions pursuant to which the prescription is dispensed shall have either:

(1) The same owner; or

(2) A written contract outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract in compliance with federal and state laws, regulations, and rules;

(b) The pharmacies shall share a database to allow access to information necessary or required to fill or refill a prescription drug order;

(c) All participating pharmacies located in this state shall maintain a pharmacy license for each location or if located in another state shall be registered in New Hampshire as a mail-order pharmacy according to Ph 900;

(d) All pharmacists participating in, providing, or both, central prescription processing services shall be licensed in this state or in the case of a non-resident pharmacy, the state in which the pharmacy is located; and

(e) Each pharmacy and pharmacist engaging in central prescription processing and handling shall be responsible for properly filling the prescription and complying with the requirements of Ph 706 or each relevant and applicable provision adopted by the state in which the pharmacy or pharmacist is registered or licensed. If such other state does not have a relevant or applicable provision, the owner or contract referred to in (a) above shall comply with or require compliance with the substance of Ph 706.

Ph 1203.02 Policy and Procedure Manual Required.

(a) Each participating pharmacy performing or contracting for the performance of centralized prescription processing and handling shall maintain a paper or electronic policy and procedure manual that includes at least the following:

(1) A policy that shall require every participating intake pharmacy to keep a record that includes at least the name, address and DEA number for each central fill or central processing pharmacy authorized to fill or process prescriptions on its behalf;

(2) A policy that shall require each central fill or central processing pharmacy to keep a record that includes at least the name, address and DEA number of all intake pharmacies for which it is authorized to fill or process prescriptions;

(3) A policy that shall describe comprehensively the responsibilities of each of the participating intake, filling, processing and dispensing pharmacies;

(4) A procedure that shall be used for maintaining records sufficient to allow for tracking a prescription during each stage of the filling and dispensing process including at least:

a. The following information about the pharmacist(s) and technician(s) involved in filling and dispensing the prescription and counseling the patient:

1. The pharmacist's full name;
2. The state in which the pharmacist is licensed and his or her license number; and
3. The action or actions taken by the pharmacist; and

b. The following information about the technician(s) involved in filling and dispensing the prescription:

1. The technician's full name;
2. The state in which the technician is licensed and the license number; and
3. The action or actions taken by the technician;

(5) The policy and procedure that shall be used for providing adequate security to protect the confidentiality and integrity of patient information;

(6) The procedure that shall be used by the pharmacy in implementing and operating a quality assurance program designed to objectively and systematically monitor, evaluate, and improve the quality and appropriateness of patient care; and

(7) The procedure that shall be followed in dispensing a prescription drug order when the filled order is not received or the patient comes in before the order is received.

(b) Each participating pharmacy and pharmacist shall review the policies and procedures at least annually and such review shall be documented.

(c) Each participating intake, processing, filling and dispensing pharmacy and pharmacist shall make the policies and procedures manual available to the board or its agents upon request.

Ph 1203.03 Patient Counseling. The dispensing pharmacy shall offer to counsel to the patient as required pursuant to Ph 706.03.

Ph 1203.04 Prohibitions and Limitations.

(a) Prescriptions for Schedule II controlled substances shall not be allowed for central prescription filling but shall be filled and dispensed at the intake pharmacy.

(b) Prescriptions for Schedule III, IV, or V controlled substances shall be allowed for central prescription processing and filling.

(c) Prescriptions for legend or controlled substances listed in Schedule III, IV, or V may be transmitted electronically, as permitted by state and federal laws, including via facsimile, from an intake pharmacy to a central fill pharmacy, provided that the intake pharmacy transmitting the prescription information complies with all state and federal laws.

(d) An intake pharmacy transmitting prescription information pursuant to (c) above shall keep:

(1) Records that track the prescription drug order during each step in the filling process that shall identify the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist or pharmacy technician who performed any portion of the process, including:

- a. Transmission;
- b. Filling;
- c. Dispensing; or
- d. Delivery to either the patient or another pharmacy; and

(2) A record of the date the filled prescription was delivered to the intake pharmacy, the method of delivery, such as by private, common or contract carrier, and the identity of the carrier.

Ph 1203.05 Record Keeping.

(a) The common electronic database shall maintain a record of all pharmacists and pharmacies involved in the intake, processing, filling, and dispensing of all prescriptions.

(b) There shall be record keeping systems between central prescription processing pharmacies with real-time, online access to those services provided by each pharmacy.

(c) Access to prescription information by 2 participating pharmacies shall not be considered a prescription transfer and not subject to the provisions of Ph 704.04.

(d) All records required to be created and maintained pursuant to Ph 1203 shall be maintained for a period of not less than 4 years.

CHAPTER Ph 1300 PHARMACIST ADMINISTRATION OF VACCINES

PART Ph 1301 PURPOSE AND SCOPE

Ph 1301.01 Purpose. The purpose of this chapter is to implement and regulate pharmacist administration of vaccines as a means to make vaccinations more easily accessible and therefore providing immunity to a larger patient population.

Ph 1301.02 Scope. These rules shall regulate pharmacist administration of vaccines where the practice of pharmacy is permitted.

PART Ph 1302 DEFINITIONS

Ph 1302.01 “Administer” means “administer” as defined in RSA 318:1, I, namely, “an act whereby a single dose of a drug is instilled into the body of, applied to the body of, or otherwise given to a person or animal for immediate consumption or use.”

Ph 1302.02 “Licensed pharmacist” or “pharmacist” means “licensed pharmacist” or “pharmacist” as defined in RSA 318:1, VII, namely, “when not otherwise limited, means a person holding a license

under RSA 318:18 and who is, therefore legally authorized to practice the profession of pharmacy in this state.”

Ph 1302.03 “Practitioner” or “licensed practitioner” means “practitioner” or “licensed practitioner” as defined in RSA 318:1, XV, namely, “means any person who is lawfully entitled to prescribe, administer, dispense, or distribute legend drugs to patients.”

PART Ph 1303 PHARMACIST ADMINISTRATION OF VACCINES QUALIFICATIONS AND APPLICATION

Ph 1303.01 Qualifications.

(a) A pharmacist who seeks to engage in the administration of vaccines shall meet the requirements of:

- (1) RSA 318:16-b, I, relative to education or experience;
- (2) RSA 318:16-b, II, relative to professional liability insurance coverage; and
- (3) RSA 318:16-b, III, relative to completion of continuing education.

(b) A pharmacist who seeks to engage in the administration of vaccines shall hold current basic or higher certification in cardiopulmonary resuscitation (CPR) from the American Heart Association, the American Red Cross, or from another organization or entity that is nationally-recognized as an issuer of such certifications.

(c) A pharmacist shall not delegate the administration of vaccines to any person.

Ph 1303.02 Application.

(a) A pharmacist who seeks to engage in the administration of vaccines shall provide the following on a “Pharmacist Administration of Vaccines Application” as specified in RSA 318:16-b, IV:

- (1) The pharmacist’s name and license number;
- (2) The pharmacist’s business and home address;
- (3) A copy of the current certificate of insurance from the pharmacist’s professional liability carrier indicating that the pharmacist maintains insurance coverage that complies with RSA 318:16-b, II;
- (4) A copy of the certificate of training as required by RSA 318:16-b, III;
- (5) A copy of the current CPR certification;
- (6) An indication that the information provided on or with the application is true, correct, and complete to the best of the pharmacist’s knowledge and belief; and
- (7) The signature of the pharmacist and the date signed.

(b) After receipt of a “Pharmacist Administration of Vaccines Application” the board’s staff shall review it for any apparent errors or omissions and inform the applicant in writing if any are found. If informed of errors or omissions, the pharmacist shall correct the error or provide the missing application materials within 30 days of such notification being sent.

(c) After receipt of a completed "Pharmacist Administration of Vaccines Application" the pharmacist shall receive an authorization letter from the board.

PART Ph 1304 PHARMACIST ADMINISTRATION OF VACCINES PROCEDURAL AND RECORDKEEPING REQUIREMENTS

Ph 1304.01 Vaccine Administration Requirements. A pharmacist who engages in the administration of vaccines shall comply with the following procedures:

(a) Provide the patient with a Vaccine Information Statement (VIS) as provided by the Centers for Disease Control (CDC);

(b) Ensure that the patient has received and signed the Patient Consent Form and has been counseled and his or hers questions answered prior to administration of the vaccine;

(c) Maintain and follow written policies and procedures that establish a course of action the pharmacist shall follow to address:

(1) Adverse reactions;

(2) Anaphylactic reactions including a standard order for treatment;

(3) Accidental needle sticks; and

(4) Handling/disposal of used or contaminated equipment and supplies;

(d) Report all adverse events to the Vaccine Adverse Events Reporting System (VAERS) and to the primary care physician if applicable;

(e) Provide the patient with documentation of the vaccination and when appropriate report it to the immunization section of the New Hampshire department of health and human services to be added to the Vaccination Registry.

(f) Provide notice electronically, in writing or fax by within 30 days to the primary care provider, when the practitioner has been designated by the patient, of the administration of the pneumococcal and varicella zoster vaccine and maintain documentation of the record for a minimum of 4 years; and

(g) Be able to recognize anaphylaxis and maintain at least 2 doses of injectable epinephrine at all times to treat a reaction if it occurs.

Ph 1304.02 Recordkeeping. A pharmacist who engages in the administration of vaccines shall, for a minimum of 4 years, keep a patient consent form that includes the:

(a) Name and date of birth of the patient;

(b) Name of the vaccine, manufacturer, lot number, and expiration date of the vaccine;

(c) Description of the risks and possible side effects of the vaccine;

(d) Date of administration;

(e) Administering pharmacist's name; and

(f) Signature of the patient.

CHAPTER Ph 1400 UNUSED PRESCRIPTION DRUG PROGRAM RULES

PART Ph 1401 PURPOSE

Ph 1401.01 Purpose: The purpose of the rule is to allow the voluntary donation of unused prescription drugs and medical devices to the uninsured and the underinsured individuals.

(a) The rules of Ph 1400 describe the program to take unused prescription drugs and medical devices donated from nursing homes, pharmaceutical manufacturers, and other eligible donors and utilize them for dispensing to uninsured and underinsured persons who opt into the program.

(b) The rules of Ph 1400 describe the eligibility to donate. They describe the eligible prescription drug formulary, the eligible recipients, and the protection for participants. They describe pharmacies eligible to accept and dispense such drugs, and medical devices the requirements for eligible pharmacies, and the responsibilities for consultant pharmacists.

(c) The rules of Ph 1400 describe safe handling of drugs and medical devices to protect drug integrity, tracking, sanitation, security and dispensing requirements for these unused prescription drugs and medical devices. The rules of Ph 1400 describe confidentiality requirements as well as violations.

PART Ph 1402 DEFINITIONS

Ph 1402.01 “Abandoned drug” means a prescription only drug that was dispensed for a patient that was never in a patient’s possession and is no longer needed by the patient or was left behind at a facility after discharge from the facility. The term includes Patient Assistance Program drugs when the manufacturer does not provide a shipping-paid option for the provider to return the drug to the manufacturer or the manufacturer’s agent and:

(a) The provider has determined and documented that the patient should not receive or is unable to receive the drug, or

(b) The patient has not returned to receive the drug within 8 weeks of the time the prescriber received the drug.

Ph 1402.02 “Agent” means any person who is legally authorized to make medical decisions for a patient.

Ph 1402.03 “Charitable Provider” means any pharmacist or practitioner licensed by this state to dispense drugs as defined by RSA 318:42 who chooses to participate in an unused prescription drug program.

Ph 1402.04 “Dispense” means to distribute, leave with, give away, dispose of, deliver, or sell one or more doses of a drug that will be administered or taken at a later date, time, or location and the transfer of more than a single dose of a medication from one container to another and the labeling or otherwise identifying a container holding more than a single dose of a drug.

Ph 1402.05 “Donate” means the giving free of charge of an eligible prescription drug to an unused prescription drug program.

Ph 1402.06 “Eligible prescription drug ” (EPD) means any unused prescription only drug that has not reached its expiration date, is contained in an unopened unit dose or other tamper evident packaging, has not been in the possession of the patient and has been stored properly and is not a radiopharmaceutical therapeutic or diagnostic drug. Drugs that can only be dispensed to a patient registered with the drug’s manufacturer in accordance with federal Food and Drug Administration (FDA) requirements are not eligible for the program.

Ph 1402.07 “Manifest” means an itemized invoice of EPD donated, accepted or destroyed.

Ph 1402.08 “Pharmacy” means “pharmacy” as defined by RSA 318:1 XI.

Ph 1402.09 “Practitioner” or "licensed practitioner" as defined by RSA 318:1 XV.

Ph 1402.10 “Program Pharmacist” means any licensed pharmacist in New Hampshire that is participating in an unused prescription drug program.

Ph 1402.11 “Redispense” means to dispense an EPD that was accepted by an unused prescription drug program for the purpose of providing medication to an individual who is uninsured/underinsured.

Ph 1402.12 “Underinsured” means a person who lacks adequate prescription related insurance coverage such that purchasing prescription drugs and/or devices create a financial hardship.

Ph 1402.13 “Uninsured” means a person who does not presently have an active insurance policy that reimburses fully or partially for prescription drugs or devices.

PART Ph 1403 ELIGIBILITY TO DONATE PRESCRIPTION DRUGS (EDP) AND MEDICAL DEVICES

Ph 1403.01 Eligible Donating Entities. The following entities shall be eligible to donate prescription drugs and medical devices:

- (a) A pharmacy;
- (b) A licensed practitioner;
- (c) A Hospice or outpatient clinic if licensed pursuant to RSA 151;
- (d) A New Hampshire nursing home, if it is licensed with the New Hampshire department of health and human services (DHHS) and has a consultant pharmacist or program pharmacist;
- (e) A licensed manufacturer/wholesaler/distributor, who voluntarily donates samples or eligible prescription drugs or medical devices to eligible charitable providers in this program; and
- (f) A state or county correctional facility if it has a program pharmacist.

Ph 1403.02 Unused Prescription Property.

(a) A prescription drug shall be the property of the patient for whom it is prescribed, regardless of who paid for the prescription.

(b) The patient or agent of the patient may at any time authorize the donation of the unused prescription drugs or medical device.

(c) An unused prescription may be donated:

(1) When a patient has died and

(2) When a drug is abandoned.

(d) Prescription drugs donated under Ph 1400 shall only be transferred to charitable providers.

(e) Prescription drugs or medical devices donated under Ph 1400 shall not be sold, resold, offered for sale, traded, or returned for financial credit. This shall not prohibit transfer between charitable providers.

(f) A charitable provider shall be responsible for determining that the patient has authorized the donation of the drugs or medical devices.

(g) A charitable provider shall make certain that the name of the patient, and all patient information and directions on the label will be redacted or removed before sending to the accepting entity to protect confidentiality.

(h) Manifests shall be maintained for internal and external transfer of product.

Ph 1403.03 Conditions Required for Unused Prescription Drugs. The following conditions shall apply to unused prescription drugs and medical devices.

(a) Licensed healthcare personnel shall in order to be eligible keep control of such unused prescription drugs and medical devices in sanitary and secure conditions as required under RSA 318:58.

(b) Such unused prescription drugs and medical devices, in sanitary and secure conditions shall be eligible for donation.

(c) Nursing homes shall have a consultant pharmacist or a program pharmacist.

PART Ph 1404 ELIGIBILITY TO ACCEPT DONATIONS (EAD)

Ph 1404.01 Eligible Accepting Entities. The following entities shall be eligible to accept unused prescription drugs and medical devices.

(a) A pharmacy;

(b) A licensed practitioner;

(c) A hospice or public health clinic including (N.H. Hospital, Glencliff Home and N.H. Veterans Home) RSA 318:58 III;

(d) New Hampshire nursing homes if they are licensed and in good standing with DHHS;

(e) A manufacturer/wholesaler/distributor may accept samples or eligible prescription drugs for eligible charitable providers in this program; and

(f) A state or county correctional facility if it has a program pharmacist or a charitable provider.

PART Ph 1405 ELIGIBILITY TO REDISPENSE

Ph 1405.01 Eligible Redispersing Entities. Entities that are eligible to redispense shall include:

- (a) A pharmacy; and
- (b) Any licensed prescriber.

PART Ph 1406 PROGRAM PHARMACIST RESPONSIBILITIES

Ph 1406.01 Program Pharmacist.

(a) All entities eligible to accept shall have the program pharmacist approved by the New Hampshire board of pharmacy.

(b) Program pharmacists for the nursing home eligible to donate unused prescription drugs and medical devices shall:

- (1) Review quality and suitability of the unused prescription drugs for reuse as follows:
 - a. The drugs and medical devices shall be kept under the control of a health care professional;
 - b. The drugs and medical devices shall be stored properly against heat, cold and moisture;
 - c. The drugs shall be identifiable; and
 - d. The drugs are not adulterated, misbranded or mutilated.
- (2) Determine that the expiration date exceeds 90 days to allow time for redistribution;
- (3) Make sure a manifest contains the following if applicable: supplier (donor) name, and receiver name, donor and receiver address, phone numbers, state permit numbers, signatures, date sent, date received, date destroyed, name, strength and dosage form of drug, NDC #, package size, quantity, initials;
- (4) Provide a copy of this manifest to the accepting entity and maintain a copy at the donating entity for at least 2 years;
- (5) Assure controlled substances, that is, Drug Enforcement Agency (DEA) controlled substances are not donated or accepted;
- (6) Assure that the accepting and donating entities are eligible to receive unused prescription drugs and medical devices under these rules; and
- (7) Have transportation of product and manifest be the responsibility of both the donating and accepting entities to ensure that product integrity is maintained.

PART Ph 1407 ELIGIBLE PRESCRIPTION DRUG FORMULARY

Ph 1407.01 Formulary. All Food and Drug Administration (FDA) approved prescription drugs excluding controlled substances shall be subject to the following:

- (a) They shall not have been in the possession of the patient or other member of the public;

- (b) They shall not have reached within 90 days of their expiration date;
- (c) They shall be contained in unopened unit dose or other tamper-evident packaging and show no evidence of contamination;
- (d) Medical devices shall not be unsanitary, broken, dangerous or otherwise unfit for practical use;
- (e) They shall not be compounded drugs;
- (f) Drugs that require storage temperatures other than normal room temperature as specified by the manufacturer shall only be donated or accepted if the program pharmacist(s) can ascertain the proper storage has been maintained at all times and transferred internally under the same ownership; and
- (g) Drugs that can only be dispensed to a patient registered with the drug's manufacturer in accordance with federal Food and Drug Administration (FDA) requirements shall not be accepted or distributed.

PART Ph 1408 REQUIREMENTS FOR PHARMACIES DISPENSING UNUSED PRESCRIPTION DRUGS

Ph 1408.01 Dispensing Requirements. Unused prescription drugs shall be dispensed in compliance with the following:

- (a) Pharmacies shall follow the requirements established in RSA 318;
- (b) New Hampshire licensed pharmacies dispensing unused prescription drugs shall:
 - (1) Maintain a current drug identification book, or shall have a current computer program or online service for the same;
 - (2) Provide information to all recipients regarding the program and maintain a participation consent form for each eligible recipient or patient representative agent of any unused prescription drug; and
 - (3) Maintain samples in the original package as required under federal law, and the samples shall not be removed from original packaging for dispensing.
- (c) If it is determined by the pharmacist's professional judgment that it would be best for the patient, the drugs can be removed from patient specific packaging or unit dose packaging (UDP), commonly referred to as bingo cards, and repackaged.
- (d) Eligible New Hampshire pharmacies shall establish the following policies and procedures for the dispensing of unused prescription drugs to the uninsured or underinsured patients as follows:
 - (1) They may limit the number of prescriptions per patient per visit or per month, to allow a greater number of individuals access to such prescription drugs;
 - (2) If no underinsured or uninsured patients are available, donated medications may be made available to other patients; and
 - (3) There shall be a written policy that is enforced equally to prevent discrimination.
- (e) Pharmacies may transfer unused prescription drugs to another pharmacy in the program when one pharmacy has the need for a drug and another pharmacy has it available. The transferring pharmacy

shall follow the rules of the donating entity and the receiving pharmacy shall follow the rules of the accepting entity.

(f) Unused prescription drugs and medical devices shall not be resold.

PART Ph 1409 RESPONSIBILITIES OF CHARITABLE PROVIDERS

Ph 1409.01 Charitable Providers. A charitable provider shall:

(a) Coordinate retrieval of donated unused prescription drugs and medical devices from entities eligible to donate;

(b) Check unused prescription drugs (UPD) against the manifest and document any discrepancies and communicate those discrepancies to the entity eligible to donate;

(c) Store and secure these UPDs in a manner that distinguishes them from general stock and store them according to state and federal laws, rules and regulations;

(d) Check the unused prescription drugs for adulteration or misbranding;

(e) Assure expired, adulterated, misbranded, and controlled drugs are not dispensed;

(f) Segregate unacceptable drugs for destruction or return and prepare a manifest that is signed by both the pharmacist and a witness when it comes time for destruction;

(g) Have access to FDA or manufacturer drug recall information. If a drug is recalled by the FDA or manufacturer and the eligible provider can not ascertain the lot number on the label to differentiate between the recall and non-recalled drug, all such donated drugs shall be considered recalled and destroyed or returned in the manner specified by the recall; and

(h) Assure destruction as defined by Department of Environmental Service of expired, adulterated, and/or recalled unused prescription medications as follows:

(1) A manifest shall be made of unused prescription drugs expired, adulterated, misbranded and/or recalled to be destroyed;

(2) Following destruction such manifest shall be signed by the pharmacist and witness verifying such destruction; and

(3) The drug destruction manifest shall be kept in the files of the pharmacy for at least 2 years.

Ph 1409.02 Labeling. Dispensed prescription(s) shall clearly indicate the final charitable provider and the current patient information to assure clarity for receiving patient and shall be properly labeled according to RSA 318:47 and shall include the expiration date.

Ph 1409.03 Handling Fee. Whenever possible the dispensing facility or service shall provide at least a 30 day supply and a handling fee may be charged according to RSA 318:58 V.

Ph 1409.04 Recordkeeping. Charitable providers shall comply with recordkeeping rules set forth by Ph 309.07.

PART Ph 1410 FORMS

Ph 1410.01 Transfer Manifests.

(a) Sample manifests shall be available by the New Hampshire board of pharmacy.

(b) All participants may use their own manifest, provided they include all current information listed on the current manifest. See Ph 1406.01 (b) (3).

PART Ph1411 PARTICIPANT IMMUNITY

Ph 1411.01 Participant Immunity. Immunity shall be provided to the program as provided in RSA 318:60.

PART Ph 1412 VIOLATIONS

Ph 1412.01 Violations of the Unused Prescription Drug Program.

(a) Theft or diversion of any of the unused prescription drugs shall be a violation of these rules. This shall include any expired, misbranded drug, adulterated drug, recalled drug, or other drug found to be unusable under the requirements of Ph 1400.

(b) Any violation by any person of the unused prescription drug program shall be reported by the licensed entity upon discovery to the appropriate licensing agency within 30 days and/or other proper authorities for possible action.

(c) Such violation by any person licensed by the board may result in action under RSA 318:55 or any licensee, permittee, registrant or certificate holder as provided in RSA 318:29.

CHAPTER Ph 1500 NEW HAMPSHIRE CONTROLLED DRUG PRESCRIPTION HEALTH AND SAFETY PROGRAM

Statutory authority: RSA 318-B:37

PART Ph 1501 PURPOSE

Ph 1501.01 Purpose. This rule implements the New Hampshire Controlled Drug Prescription Health and Safety Program created by RSA 318-B:31–38, which authorizes the pharmacy board to establish and contract with a third party for the implementation and operation of an electronic system to facilitate the confidential sharing of information relating to the prescribing and dispensing of schedule II–IV controlled substances by prescribers and dispensers within the state to promote public health and safety through the prevention of and treatment for misuse and abuse of controlled substances and the reduction of the diversion of such substances, without interfering with the legal medical use of these substances.

PART Ph 1502 DEFINITIONS

Ph 1502.01 Definitions.

(a) “Authorized representative” means a parent or guardian of a minor child, or a person who has been authorized in the manner required by law to make health care decisions, or gain access to health care records, on behalf of another.

(b) “Board” means “board” as defined in RSA 318-B:31, I, namely, “the pharmacy board, established in RSA 318:2.”

(c) “Controlled substance” means “controlled substance” as defined in RSA 318-B:31, II, namely, “controlled drugs as defined in RSA 318-B:1, VI.”

(d) “Credential” means information or a device provided by the program to a registered dispenser or prescriber that allows the dispenser or prescriber to electronically submit or access prescription monitoring information. Credentials include, but are not limited to, a user name and password, or an identification device that generates a user name and password.

(e) “Dispense” means “dispense” as defined in RSA 318-B:31, III, namely, “to deliver a controlled substance by lawful means and includes the packaging, labeling, or compounding necessary to prepare the substance for such delivery.”

(f) “Dispenser” means a person or entity lawfully authorized to deliver a schedule II-IV controlled substance, but does not include:

- (1) A licensed hospital pharmacy that dispenses for administration in the hospital;
- (2) A practitioner, or other authorized person who administers such a substance; or
- (3) A wholesale distributor of a schedule II–IV controlled substance or its analog.

(g) “Patient” means “patient” as defined in RSA 318-B:31, V, namely, “the person or animal who is the ultimate user of a controlled substance for whom a lawful prescription is issued and for whom a controlled substance or other such drug is lawfully dispensed.”

(h) “Practitioner” means a physician, dentist, podiatrist, veterinarian, pharmacist or other person licensed or otherwise permitted to prescribe, dispense, or administer a controlled substance in the course of licensed professional practice.

(i) “Prescribe” means “prescribe” as defined in RSA 318-B:31, VII, namely, “to issue a direction or authorization, by prescription, permitting a patient to lawfully obtain controlled substances.”

(j) “Prescriber” means “prescriber” as defined in RSA 318-B:31, VIII, namely, “a practitioner or other authorized person who prescribes a schedule II, III, and/or IV controlled substance.”

(k) “Program” means “program” as defined in RSA 318-B:31, IX, namely, “the controlled drug prescription health and safety program that electronically facilitates the confidential sharing of information relating to the prescribing and dispensing of controlled substances listed in schedules II-IV, established by the board pursuant to RSA 318-B:32.”

(l) “Program manager” means the person designated by the board to oversee the implementation and operation of the program by the program vendor.

(m) “Program vendor” means a third party with which the board contracts for the implementation and operation of the program.

(n) “Regulatory board” means the New Hampshire board of dentistry, board of medicine, board of nursing, board of registration in optometry, board of podiatry, board of veterinary medicine, and pharmacy board.

PART Ph 1503 REGISTRATION OF PRESCRIBERS AND DISPENSERS

Ph 1503.01 Registration of Prescribers and Dispensers.

(a) All practitioners authorized to prescribe or dispense schedule II–IV controlled substances within the state of New Hampshire shall register with the program no later than June 30, 2015.

(b) Program registration shall be by one of the following methods:

(1) Automatic registration at the time of the program go-live date or at the time of initial licensure or license renewal, if permitted by the prescriber’s or dispenser’s regulatory board; or

(2) Completing and submitting to the program vendor a registration form provided by the program vendor.

(c) Before a program credential is issued, the registrant shall be verified as having a current and valid license, as follows:

(1) Those prescribers and dispensers who register in accordance with (b)(1) above shall be automatically verified; and

(2) Those prescribers and dispensers who register in accordance with (b)(2) above shall be verified by the program manager by confirming that the registrant has a valid license.

(d) On a monthly basis, each regulatory board shall submit to the program manager or program vendor a list of prescribers and dispensers:

(1) Who have been issued a new license;

(2) Whose license has been renewed; and

(3) Who have had their license revoked, suspended, restricted, or not renewed.

(e) If the credentials issued by the program vendor are lost or missing, or if the security of the credentials is compromised, the prescriber or dispenser shall cause the program manager to be notified by telephone and in writing as soon as possible.

(f) Those dispensers licensed under RSA 318 who have not registered by June 30, 2015 shall be subject to disciplinary action as established pursuant to RSA 318:29.

(g) Those prescribers who are required to register who have not registered by June 30, 2015 shall, pursuant to RSA 318-B:36 III, be subject to penalties established by their respective regulatory board.

PART Ph 1504 REQUIREMENTS FOR DISPENSERS

Ph 1504.01 Reporting of Controlled Substances Dispensed.

(a) Dispensers shall submit to the program the prescription drug monitoring information required by RSA 318-B:33, IV, and paragraph (b) below, for each dispensing of a schedule II–IV controlled substance, as follows:

- (1) Electronically, unless a waiver is requested and granted in accordance with Ph 1504.02 below;
 - (2) Within 7 days of the controlled substance being dispensed, unless an extension is requested and granted in accordance with Ph 1504.03 below; and
 - (3) For registered dispensers located outside the state of New Hampshire, information only for patients who reside in New Hampshire.
- (b) The required prescription drug monitoring information to be submitted shall be as follows:
- (1) Dispenser's Drug Enforcement Administration (DEA) registration number and, if available, the dispenser's National Provider Identification (NPI) number;
 - (2) Prescriber's DEA registration number and, if available, the prescriber's NPI number;
 - (3) Date of dispensing;
 - (4) Prescription number;
 - (5) Number of refills granted;
 - (6) National Drug Code (NDC) of drug dispensed;
 - (7) Quantity dispensed;
 - (8) Number of day's supply of drug;
 - (9) Patient's name, including first name, middle initial, if applicable, last name, and, suffix, if applicable;
 - (10) Patient's address;
 - (11) Patient's date of birth;
 - (12) Patient's phone number, if available;
 - (13) Date prescription was written by prescriber;
 - (14) Whether the prescription is new or a refill; and
 - (15) Source of payment for prescription.

(c) Dispensers licensed by the board under common ownership, including those located outside of New Hampshire, may submit the required prescription drug monitoring information in (b) above in a single joint report provided that each dispenser is clearly identified for each prescription dispensed.

(d) The program vendor shall perform data checks to ensure that the required prescription drug monitoring information submitted is accurate, complete, and timely.

(e) The program vendor shall notify the dispenser, the program manager, and the board:

- (1) When the dispenser fails to submit the required prescription drug monitoring information within the required timeframe;
 - (2) When there are inaccuracies or omissions in the required prescription drug monitoring information submitted; and
 - (3) When a dispenser fails to correct any inaccuracies or omissions.
- (f) Dispensers shall:
- (1) Correct any failures, inaccuracies, or omissions, within 7 days of the date of receipt of notice from the program vendor.
 - (2) Correct their own records and submit corrected information to the program or program vendor whenever they become aware of errors, omissions, or reversals.
 - (3) Comply with any provision of this section or be subject to disciplinary action as established pursuant to RSA 318:29.

Ph 1504.02 Waivers.

- (a) Dispensers that are unable to submit by electronic means the required prescription drug monitoring information may request a waiver to submit the information by other means by submitting a waiver request to the program manager, along with any supporting documentation.
- (b) A waiver request submitted pursuant to this section shall:
 - (1) Demonstrate that, for any reason, including low volume of controlled substances being dispensed, financial hardship will result from the requirement of electronic submission.
 - (2) Include an alternative method by which the dispenser will submit the required prescription drug monitoring information with the time frame specified in Ph 1504.01(a)(2). Alternative methods of submission include, but are not limited to, program vendor website, e-mail, flash drive, CD, or paper.
- (c) Dispensers shall be notified of the decision to grant a waiver within 30 days of the date of the receipt of the completed waiver request.
- (d) A waiver shall be non-transferable.
- (e) A waiver shall be time-limited, not to exceed the dispenser's license expiration date.
- (f) A waiver shall be subject to revocation if the bases for granting the waiver are determined to be no longer true.

Ph 1504.03 Extensions.

- (a) Dispensers that are unable to submit required prescription information within the required timeframe may request from the program manager an extension of the timeframe by telephone confirmed by email from the program manager.

(b) The program manager shall allow an extension for as long as the dispenser is making a good-faith effort to submit the required information, but no later than 10 calendar days after the established 7 day timeframe.

(c) The program manager shall notify the board if a dispenser ceases to demonstrate good faith in its efforts to submit the required information or if the dispenser fails to submit the required information by the extended timeframe.

PART Ph 1505 ACCESS TO PRESCRIPTION DRUG MONITORING INFORMATION

Ph 1505.01 Patient Access.

(a) A patient for whom a prescription for a schedule II–IV controlled substance is dispensed, or his or her authorized representative, may request and obtain a report listing all prescription monitoring information that pertains to that patient.

(b) The request in (a) above shall be submitted to the program manager, either by mail or in person, on a complete, “Patient Prescription Monitoring Information Request” form (February 2014 Edition) signed by the patient, or the patient’s authorized representative.

(c) Patient information shall not be mailed or otherwise transmitted to the patient, or the patient’s authorized representative, except as allowed by (d) below.

(d) Upon notice that the requested information is available, the patient, or the patient’s authorized representative, shall receive the information in person, only after he or she produces valid government-issued photographic proof of identity. The patient, or the patient’s authorized representative, shall allow the photocopying of the identification.

Ph 1505.02 Prescriber and Dispenser Access.

(a) Registered prescribers and dispensers shall have electronic program access to information on a specific patient, and in the case of veterinarians a specific patient’s owner(s), both past and present, for which a prescription was written or an appointment was scheduled or conducted.

(b) Registered prescribers and dispensers for whom a waiver is requested and granted in accordance with Ph 1504.02 shall have program access to information as described in (a) above by written request in accordance with (c) through (e) below.

(c) Requests shall be made by electronic or written request.

(d) Electronic requests shall be made through the program’s secure web portal.

(e) Written requests shall:

(1) Be made by submitting to the program a completed “Prescriber/Dispenser Prescription Monitoring Information Request” form (February 2014 Edition); and

(2) Be fulfilled by secure mail or fax.

(f) To enable the timely and efficient delivery of medical or pharmaceutical care for a specific patient, a prescriber or dispenser registered with the program may delegate the task of retrieving program information for a specific patient to an individual working under the direction and supervision of the

registered prescriber or dispenser provided that written documentation of the delegation to the individual is provided to the program. Both the prescriber or dispenser who authorized the delegation and the individual to whom the task of retrieving the program information was delegated shall be subject to the provisions and penalties in RSA 318-B:36 regarding proper access to and use of program information.

Ph 1505.03 Law Enforcement Access.

(a) Authorized law enforcement officials may request and obtain information from the program on a case-by-case basis for the purpose of investigation and prosecution of a criminal offense.

(b) For the purposes of (a) above, a law enforcement official shall be considered authorized if he or she provides a court order based on probable cause, or a search warrant signed by a judge, which includes sufficient information to correctly identify the patient, prescriber, or dispenser whose prescription monitoring information is the subject of the court order.

(c) A law enforcement official shall present the court order or search warrant to the representative of the board designated by the board to receive such orders, who shall notify the program manager to provide the information identified in the court order in the format requested by the court order.

Ph 1505.04 Regulatory Board Access.

(a) New Hampshire regulatory boards, and equivalent out-of-state boards, may request and obtain information from the program, provided, however, that the request is pursuant to the regulatory board's official duties and responsibilities and the disclosures to each regulatory board relate only to its licensees and only with respect to those licensees whose prescribing or dispensing activities indicate possible fraudulent conduct.

(b) Requests in (a) above shall be in writing, signed by the regulatory board's executive director, investigator, or other person authorized to discharge equivalent functions of the regulatory board, and sent to the program manager.

(c) The address for the program shall be:

Pharmacy Board
Program Manager
Prescription Drug Monitoring Program
121 South Fruit Street
Concord New Hampshire 03301

Ph 1505.05 Other Access.

(a) Out-of-state prescription drug monitoring programs may request and obtain information from the program on a case-by-case basis provided that an agreement is in place with the other state to ensure that the information is used and disseminated pursuant to the applicable requirements of the NH controlled drug prescription health and safety program.

(b) Requests in (a) above shall be in writing, signed by the director of the out-of-state prescription drug monitoring program, or designee, and sent to the program manager at the address in Ph 1505.04(c).

PART Ph 1506 REVIEW AND REPORTING OF PRESCRIPTION DRUG MONITORING INFORMATION

Ph 1506.01 Review of Program Data.

(a) The program vendor shall collect and monitor all prescription drug monitoring information required by RSA 318-B:33, IV, and Ph 1504.01(b).

(b) The program vendor shall review and evaluate the collected information in order to identify behavior that suggests possible drug abuse, misuse, or diversion, or possible violations of law or breaches of professional standards.

(c) The program vendor shall consider, at a minimum, the following patient-related factors in its evaluation in (b) above:

- (1) Number of in-state prescribers;
- (2) Number of out-of-state prescribers;
- (3) Number of prescriptions;
- (4) Number of doses;
- (5) Overlapping prescriptions;
- (6) Unhealthy combinations of controlled substances;
- (7) Method of payment;
- (8) Number and frequency of pharmacies used; and
- (9) Dangerous levels of controlled substances.

(d) The program vendor shall consider, at a minimum, the following prescriber/dispenser-related factors in its evaluation in (b) above:

- (1) Number of prescriptions;
- (2) Number of doses;
- (3) Overlapping prescriptions;
- (4) Unhealthy combinations of controlled substances;
- (5) Number and frequency of pharmacies used;
- (6) Dangerous levels of controlled substances;
- (7) Electronic program access and use; and
- (8) For dispensers only, method of payment.

Ph 1506.02 Reporting of Program Data.

(a) The program shall report to the appropriate regulatory boards identified in RSA 318-B:35, I(b)(2), relevant information to be used by the regulatory board for further investigation:

(1) When there is cause to believe a potential violation of law or a breach of professional standards may have occurred; and

(2) When there is cause to believe that a failure to report the dispensing of a schedule II–IV controlled substance conceals a potential pattern of diversion of controlled substances into illegal use.

(b) The program shall notify prescribers and dispensers:

(1) When there is cause to believe a potential violation of law or a breach of professional standards may have occurred, unless such notice is likely to interfere with an investigation conducted by the regulatory board; and

(2) When there is cause to believe a patient might be obtaining prescriptions in a manner that may represent misuse or abuse of controlled substances, including obtaining controlled substances from multiple practitioners or dispensers.

(c) The program vendor shall report to the board on at least a quarterly basis all the reports made in (a) and (b) above.